ENGLISH

ORTHOPANTOMOGRAPH® OP300

Digital Panoramic X-Ray System

User Manual

203887 rev. 5

Copyright

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1 Introduction

1.1 ORTHOPANTOMOGRAPH® OP300

INSTRUMENTARIUM DENTAL®
ORTHOPANTOMOGRAPH® OP300 x-ray unit (hereafter called “OP300”) is a dental x-ray system for producing high quality digital images of dentition, TM-joints and skull. In order to take images with OP300 you need a suitable PC hardware connected to the OP300 unit and CLINIVIEW™ software (or suitable third party software via TWAIN driver) to capture and manage images.

OP300 performs the following procedures:

Panoramic

- Standard panoramic
- Pediatric panoramic
- Wide arch panoramic
- Bitewing
- TMJ, PA projection
- Ortho TMJ, axial corrected lateral projection
- Maxillary sinus
- Ortho Zone enhanced panoramic
- Orthogonal panoramic

Cephalometric (optional)

- Cephalometric lateral projection
- Cephalometric pediatric lateral projection
- Cephalometric postero-anterior (PA) projection
- Reverse Towne projection
- Waters view
- Carpus program (optional)
  (Not available in USA and Canada)

3D (optional)

- 61x41 mm Field of View
- 61x78 mm Field of View
- Endo 61 x 41 mm Field of View

1.2 References

The following instructions are delivered with in the OP300 installation manual:

- Firmware update instructions
- Calibration instructions
- Cephalostat upgrade instructions
- Cephalostat side changing instructions

The following instructions are separate and can be ordered from customer service:

- 3D upgrade instructions are delivered with the 3D upgrade kit

1.3 Intended use

OP300 must only be used and operated by dentist and other qualified professionals. OP300 must only be used to take panoramic, cephalometric and 3D images of the dento-maxillofacial complex of the human skull. It must not be used to take images of any other part of the human body.

Panoramic and 3D exposures should not be used if conventional intraoral radiographic images (bitewing exposures) would be sufficient.

Cone beam computed tomography images are not adequate for the analysis of soft tissue.

CAUTION! *USA only: Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.*

1.4 Associated documentation

- OP300 user manual
- OP300 installation manual
- The CLINIVIEW™ software user manual
- The CLINIVIEW™ software installation manual
- The user manual supplied with the dental imaging software
- The installation manual supplied with the dental imaging software
- The user manual supplied with the 3D imaging software
- The installation manual supplied with the 3D imaging software

1.5 Abbreviations used in this manual

FOV = Field Of View. The cylindrical 3D volume that is reconstructed by the system.

ROI = Region Of Interest. The anatomical area or region of the patient that you are interested to examine.

FH = Frankfort-Horizontal

H = Horizontal

1.6 Warnings and precautions

1.6.1 Warnings to be observed during use

The unit may be dangerous to the user and the patient, if the safety regulations in this manual are ignored, if the unit is not used in the way described in this manual and/or if the user does not know how to use the unit.

The unit must only be used to take the dental x-ray exposures described in this manual. The unit must NOT be used to take any other x-ray exposures. It is not safe to use the unit to take x-ray exposures, that it is not designed for.

Only professionally qualified dental and/or medical personnel are allowed to operate the unit and carry out any diagnoses based on output from the unit.

Because the x-ray limitations and safety regulations change from time to time, it is the responsibility of the user to make sure that all the valid safety regulations are fulfilled.

When taking an x-ray exposure of a patient with exceptional anatomy (typically very tall or large) use the Test-mode (no x-rays) first to make sure that patient can be positioned correctly to the unit and for checking that the unit doesn't hit the patient.

Operator should maintain visible contact with the patient and technique factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.

It is the responsibility of the doctor to decide whether x-ray exposure or any additional exposures are justified and necessary.

The minimum height of patient that can be x-rayed is 120 cm (3.9ft / 47.2in) and the maximum is 200 cm (6ft /78in). These heights only apply to patients with normal anatomy.

Always use the lowest suitable x-ray dose to obtain the desired level of image quality.

Avoid taking x-ray exposures of pregnant women.

When taking an x-ray exposure of a child always use the lowest possible x-ray dose, the smallest possible image area and the lowest possible resolution that allows you to perform the required diagnostic task.

If the patient is using a pacemaker, consult the manufacturer of the pacemaker before taking an exposure to confirm that the x-ray unit will not interfere with the operation of the pacemaker.

Decontaminate all the surfaces that the patient is in contact with after every patient to prevent cross infection.

Decontaminate all device accessories that contact the patient during a radiographic examination.

Do not open or remove any of the unit's enclosures. No user serviceable parts inside.

The customer must ensure that the siting environment fulfills the requirements listed in the Installation manual. Special attention must be paid to the strength of the floor and wall materials, electrical mains and radiation protection. It is the responsibility of the customer to ensure that the site is large enough for the patients.

The unit contains toxic materials that need to be handled properly when disposing the unit. Return the unit to the dealer in the end of its life cycle.

Excessive dust should be cleaned from the unit for free airflow and cooling. Switch of the unit before cleaning.

Always follow the instructions for patient positioning and imaging procedures instructed in the User Manual.

1.6.2 Warnings for cross infection

Always use available disposable protective covers with the patient positioning accessories:
Bite fork cover
Chin support cover
Head support cover
Nose support cover
Ear holder cover

1.6.3 General warnings

Personnel operating the device must be adequately trained with respect to the technological principles of operation and radiation protection when using cone beam computed tomography (CBCT) imaging.

This unit complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. shall not be used in close proximity of the unit as they could influence the performance of the unit.

The correct software and settings in the workstation are essential to the performance of the unit. Consult technical support to ensure correct setup.

Danger: Explosion hazard - do not use in the presence of flammable anesthetics, gases or vapors.

The unit is factory set to operate using a 230-240 ±10 VAC power supply. Never connect the unit to a power supply different to the voltage marked on the unit.

The site must fulfill the environmental requirements in the installation manual chapter technical specifications.

There should be free space around the unit for safe operation.

To maintain patient safety it is mandatory to use an unshielded CAT6 Ethernet cable between the unit and the network or workstation, so that multiple chassis are not connected. Non-medical grade PC should not be used in patient environment.

This product itself complies with IEC 60601-1 medical safety standard but in order to the system incorporating also a PC to comply the standard, EITHER the PC has to be a medical PC OR the PC has to be located over 1,5 meters apart from the unit. The installer and the user of the system shall confirm that at least one of the above requirements is fulfilled. A PC is a medical one if it complies IEC 60601-1 standard and that is indicated in the accompanying documents of the PC. See chapter Technical specifications, Minimum PC Requirements, in user manual.

All service operations must be made by authorized service personnel only.

The annual service as described in manual is mandatory for the correct and safe operation of the unit.

When taking exposures, operators and service personnel must protect themselves from radiation and remain at least two meters (six feet) away from the unit during exposure. Protect the patient from scattered radiation by placing a protective lead apron over the patient.

The unit must be installed and serviced according to the unit Installation & adjustments manual by a qualified technician.

Only personnel trained and approved by the manufacturer of the unit are allowed to service the unit.

3D should not be used for routine or screening examinations in which a radiograph is taken regardless of the presence or absence of clinical signs and symptoms. 3D imaging examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.

Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the imaging should be done using conventional medical CT or MR, rather than 3D imaging using Cone Beam technology.

Make sure that patient's thyroid glands are protected by a lead apron during the exposure.

The place where the unit is to be installed and the position from where the user will take exposures must be correctly shielded from the radiation that is generated when the unit is operated. Ensure to fulfill or exceed the requirements of your local regulations.

The unit or its parts must not be changed or modified in any way without approval and instructions from the manufacturer.

When servicing use only approved replacement parts supplied by the manufacturer.

The use of accessories not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

If this device is used with 3rd party imaging application software not supplied by the manufacturer, the 3rd party imaging application software must comply with all local

laws on patient information software. This includes the Medical Device Directive 93/42/EEC and/or relevant legal requirements in the USA.

Do not connect any equipment to the unit that has not been supplied with the unit or that is not recommended by the manufacturer. The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

Correct sharp layer should be chosen when using multilayer PAN images. See user manual chapter Multilayer PAN images for correct procedure.

1.7 Disclaimer

The manufacturer shall have no liability for consequential damages, personal injury, loss, damage or expense directly or indirectly arising from the use of its products. No agent, distributor or other party is authorized to make any warranty or other liability on behalf of the manufacturer with respect to its products.

1.8 Disposal

The device, its spare parts, its replacement parts and its accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

Unit has at least the following parts that should be regarded as nonenvironmental friendly waste products:

- Tubehead (Pb, oil)
- Collimator (Pb)
- All electronic circuits, electronic boards inside
- Sensor covers (EMC painted)

2 Unit description

2.1 Main parts and controls

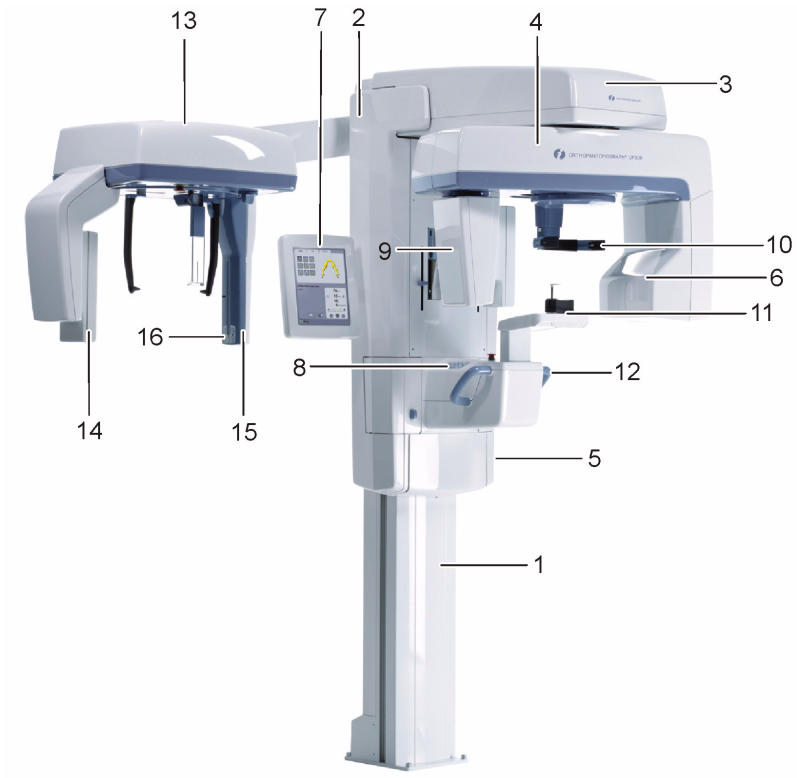
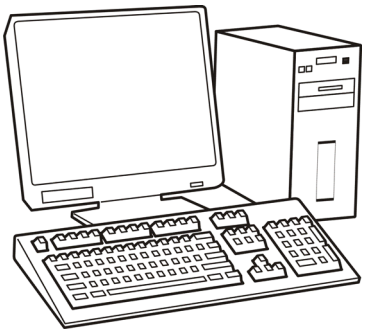


Fig 1.1.

1. Column
2. Carriage
3. Main support
4. Rotating unit
5. On/off switch (rear of carriage) and main fuses
6. Tubehead assembly
7. Touch screen display
8. Positioning panel
9. Sensor head
10. Head support
11. Chin rest
12. Handles
13. Cephalostat unit
14. Cephalostat sensor
15. Secondary collimator
16. Positioning panel

Fig 1.1.
On/off switch and main fuses



PC with MDD approved dental imaging software and 3D viewing software (not included).

All software must conform to the MDD and the relevant legal requirements in the USA.

The PC must conform to all the unit and dental imaging software requirements.

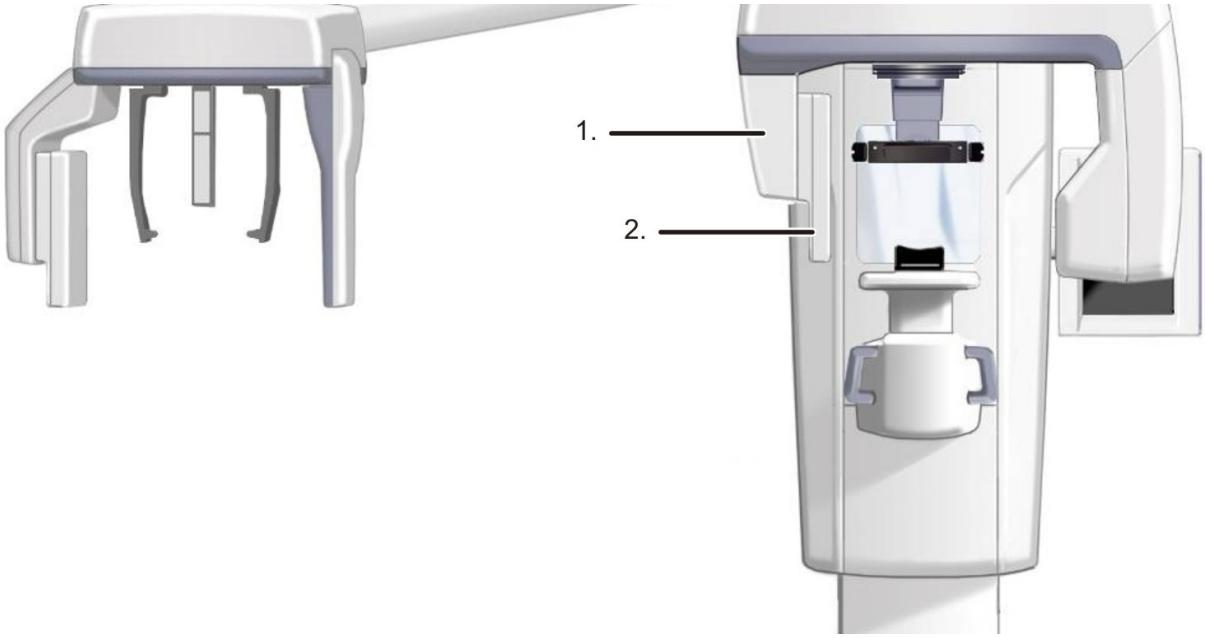


Fig 1.2.

1. Sensor holder (units without 3D option)
2. Panoramic sensor

Fig 1.3.

1. 3D sensor (units with 3D option)
2. Panoramic sensor

2.2 Patient positioning lights

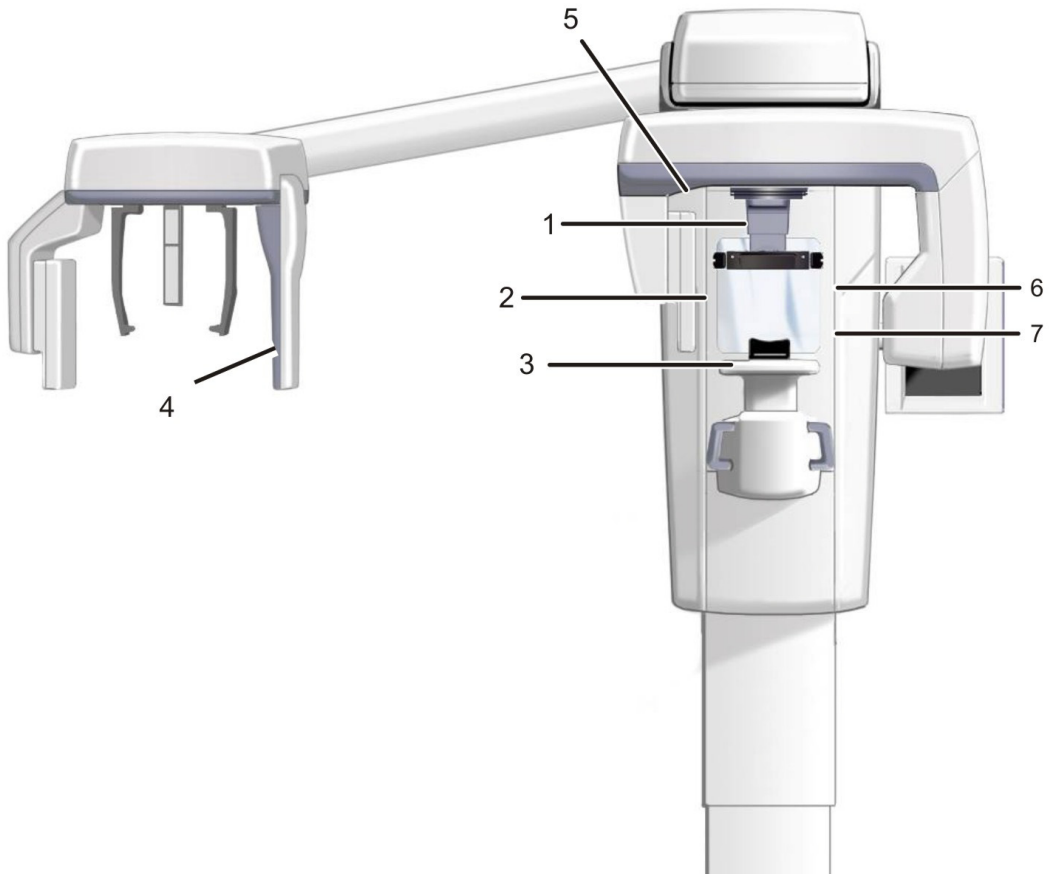


Fig 1.4.

1. Midsagittal light
2. Frankfort horizontal (FH) light
3. Image layer light
4. Cephalometric FH light
5. TMJ light
6. Horizontal light, top of FOV (3D option only)
7. Horizontal light, bottom of FOV (3D option only)

Panoramic lights

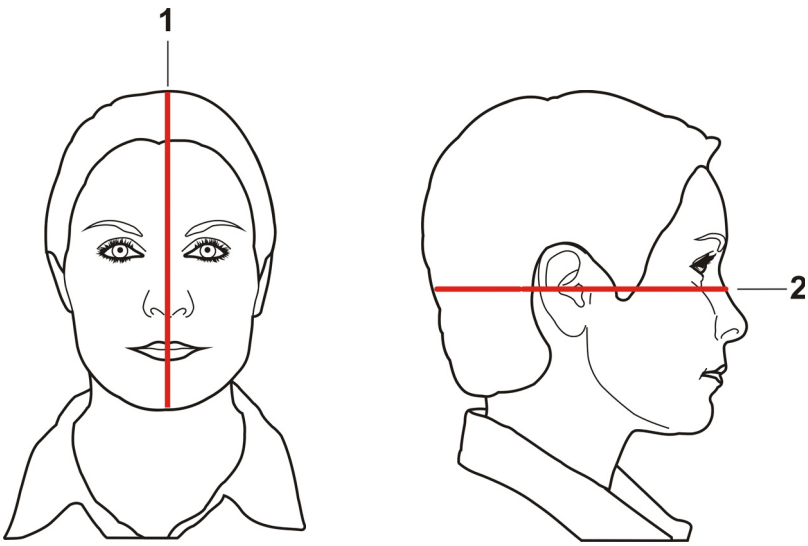


Fig 1.5.

1. Midsagittal light
2. FH light

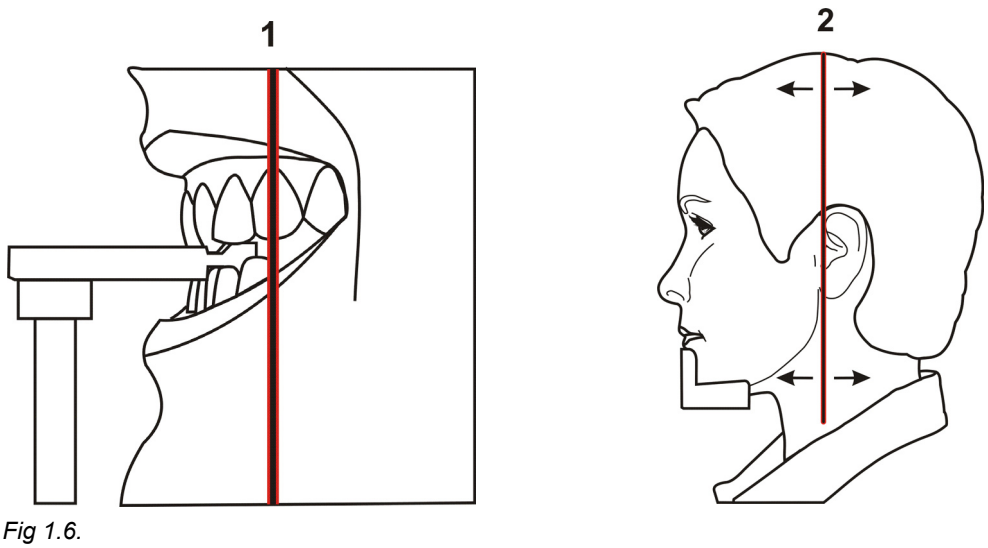


Fig 1.6.

1. Image layer light
2. TMJ light

Cephalometric lights

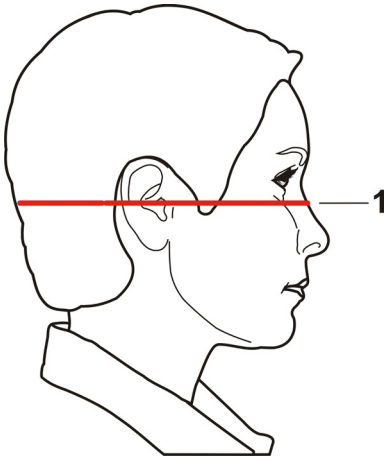


Fig 1.7.

1. FH light

3D lights

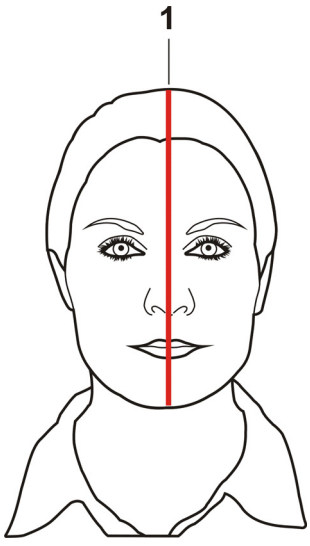
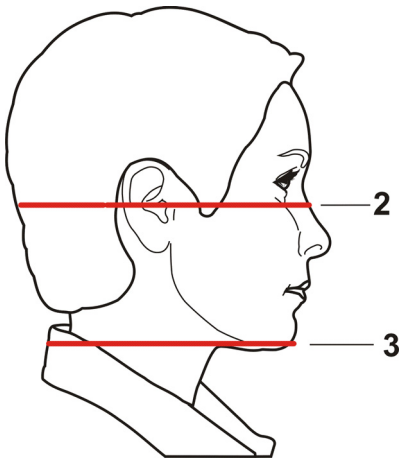


Fig 1.8.



1. Midsagittal light
2. Horizontal light, top of FOV
3. Horizontal light, bottom of FOV

2.3 Patient positioning panel

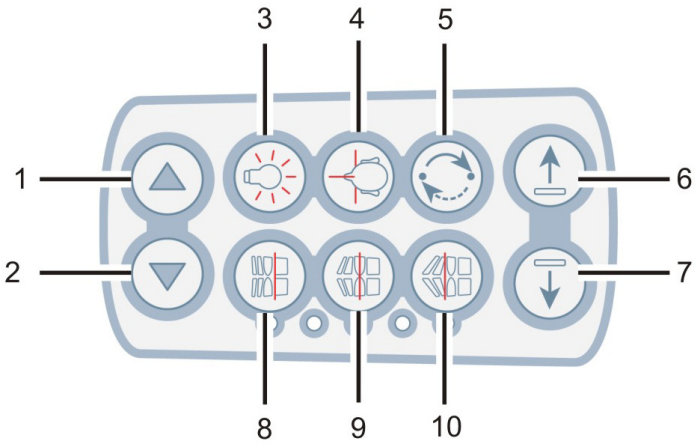
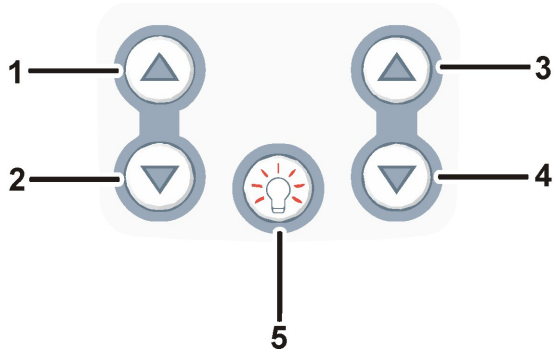


Fig 1.9.

1. Carriage UP
2. Carriage DOWN
3. Positioning lights ON/OFF
4. Patient positioning
5. Start positioning
6. Chin support UP
7. Chin support DOWN
8. Move the image layer anterior before exposure 3 mm, with sinus program 10 mm
9. Normal occlusion/ reset position
10. Move the image layer posterior before exposure 3 mm, with sinus program 10 mm

2.3.1 Cephalometric unit



1. Carriage UP
2. Carriage DOWN
3. Carriage UP
4. Carriage DOWN
5. Positioning lights ON/OFF

2.4 Emergency stop switch

In case of malfunction of the exposure button or other protective devices of the unit, an emergency stop switch is provided near the handles and on the roof of the cephalostat head so that the patient can reach it.

If the emergency stop switch is pressed during an exposure, the exposure is terminated immediately and the x-ray unit is completely stopped. An interrupted exposure cannot be continued later, but has to be retaken from the beginning.

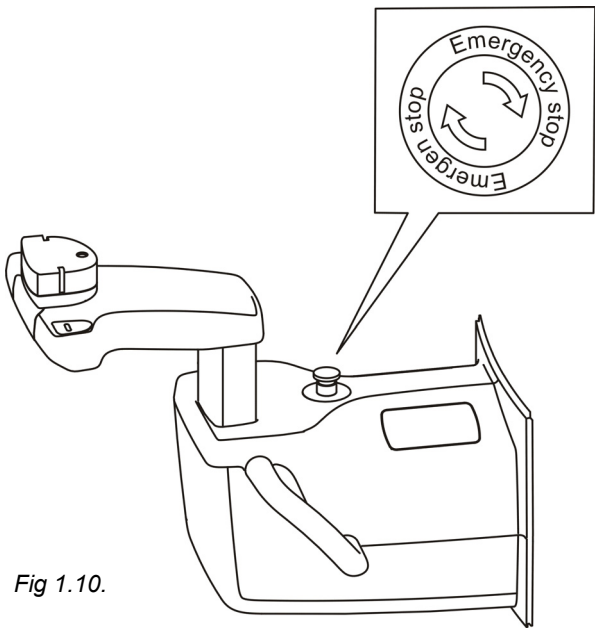


Fig 1.10.

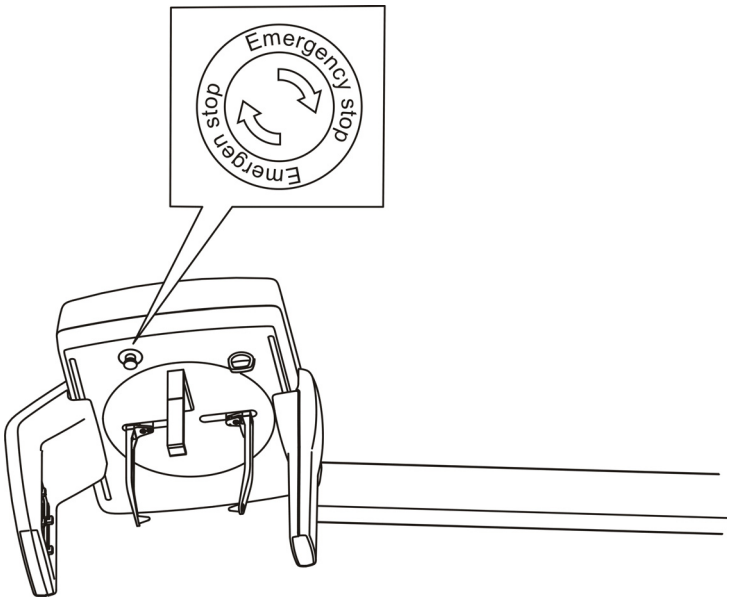


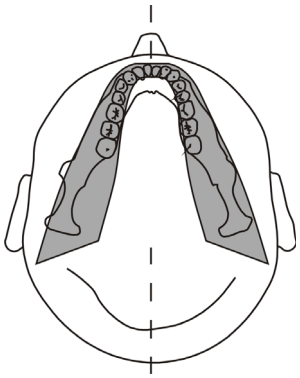
Fig 1.11.

Press to stop the unit, rotate to release.

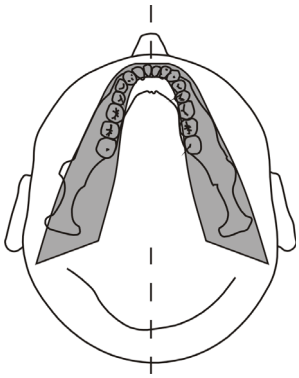
3 Imaging programs

3.1 Panoramic programs

Standard: Magnification 1.3



Exposure settings for panoramic program				
100 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
230 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				

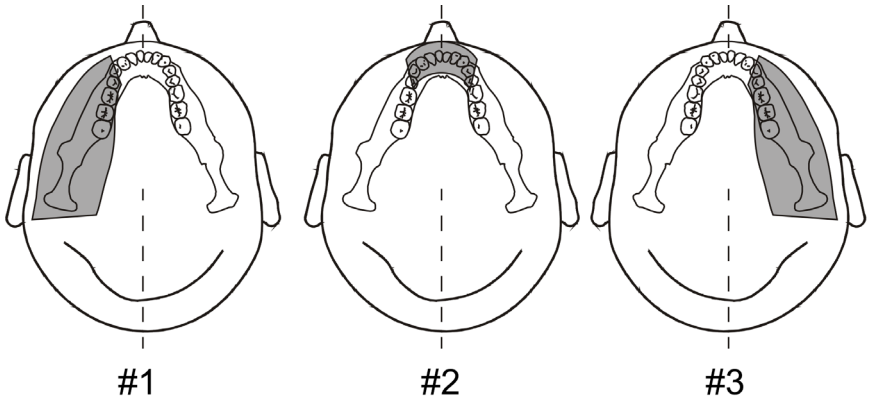


Pediatric: Magnification 1.3

Exposure settings for pediatric program				
100 VAC	66 kV/4 mA	66 kV/6.3 mA	66 kV/8 mA	70 kV/10 mA
230 VAC	66 kV/4 mA	66 kV/6.3 mA	66 kV/8 mA	70 kV/10 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				

Pediatric patients can be imaged with less radiation dosage and shorter exposure time. Patients with jaw more narrow than average jaw can be exposed with this procedure too.

Ortho Zone: Magnification 1.25



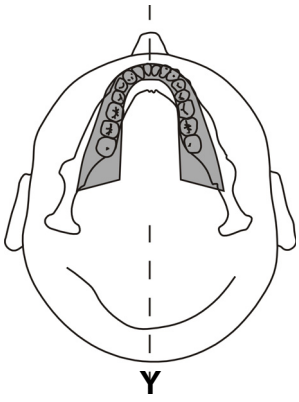
The Ortho Zone program produces two different scanning geometries combined in the same image.

The first geometry (#1 and #3 in the figure) gives a standard panoramic view of the molar region.

The result of this scanning location will allow for views of the TM joint and molar area without redundant shadows from the opposite side ramus obscuring the image. Patients with prosthetic condyles or other posterior radio opaque objects can have the opposite side successfully imaged.

The second view (#2 in the figure) produces an image of the anterior region with a very wide layer of focus (approx. 35 mm). This view may be helpful when diagnosing trauma, wired shut, severe class III malocclusion and uncooperative patients.

Exposure settings for Ortho Zone program				
100 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
230 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				

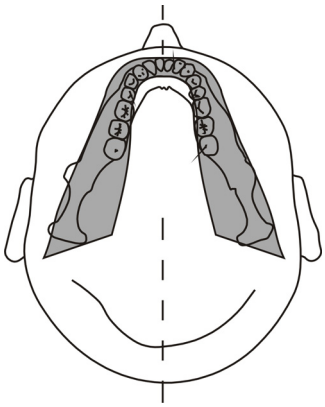


Orthogonal: Magnification 1.3

An optimized view of the dentition only with optimized angulation and reduced radiation.

Orthogonal program produces a panoramic view with modified projection geometry. The Y axis of the rotation path is changed to improved the beam angle to be closer to 90° to the interproximal surfaces. With this improvement, other trade off's must be made. The ascending rami may be lost and in adult patients and redundant shadows will be increased.

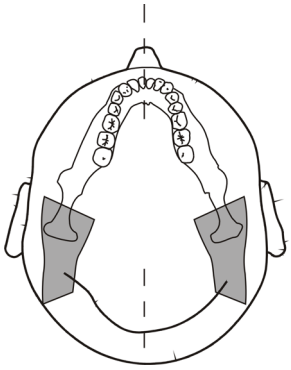
Exposure settings for Orthogonal program				
100 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
230 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				



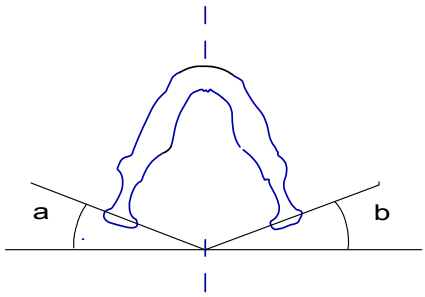
Wide arch: Magnification 1.3

Used when the patient has a wider than normal dental arch.

Exposure settings for Wide arch program				
100 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
230 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				



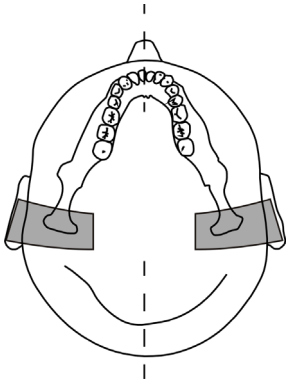
Ortho Lateral TMJ: Magnification 1.23



Ortho TMJ program provides a wide layer axially corrected views for the patient's left and right temporomandibular joints.

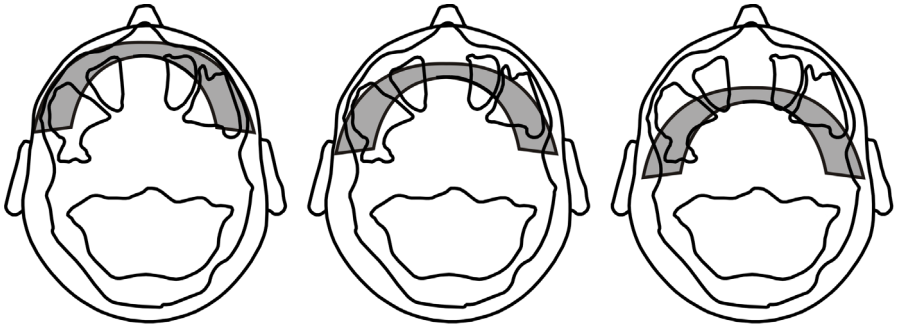
Exposure settings for Ortho Lateral TMJ program				
100 VAC	73 kV/6.3 mA	73 kV/10 mA	73 kV/13 mA	73 kV/16 mA
230 VAC	73 kV/6.3 mA	73 kV/10 mA	73 kV/13 mA	73 kV/16 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				

PA TMJ: Magnification 1.55



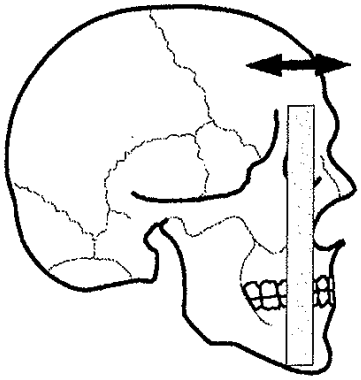
Exposure settings for PA TMJ program				
100 VAC	73 kV/6.3 mA	73 kV/10 mA	73 kV/13 mA	73 kV/16 mA
230 VAC	73 kV/6.3 mA	73 kV/10 mA	73 kV/13 mA	73 kV/16 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				

Maxillary Sinus: Magnification 1.3

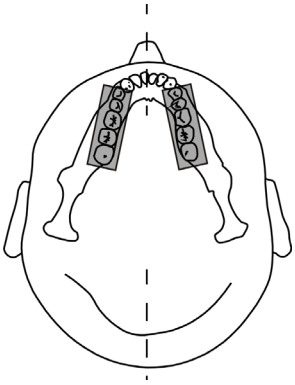


Mesial 10 mm Start Distal 10 mm

Maxillary Sinus program produces a pan - tomographic layer through the posterior maxillary sinus. The layer is flatter than the standard panoramic programs and is moved 18 mm backward. These images are helpful in visualizing the mid and posterior maxillary sinus.



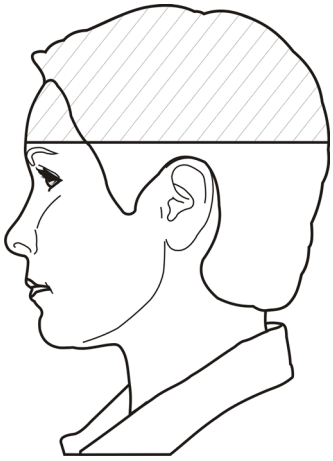
Exposure settings for Maxillary Sinus program				
100 VAC	66 kV/6.3 mA	66 kV/10 mA	66 kV/13 mA	73 kV/13 mA
230 VAC	66 kV/6.3 mA	66 kV/10 mA	66 kV/13 mA	73 kV/13 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				



Bitewing: Magnification 1.3

An orthogonal view of the dentition from the canine and posterior.

Exposure settings for Bitewing program				
100 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
230 VAC	66 kV/5 mA	66 kV/8 mA	66 kV/10 mA	70 kV/13 mA
Note! *Patient size adult (third from the left) is the default exposure setting.*				

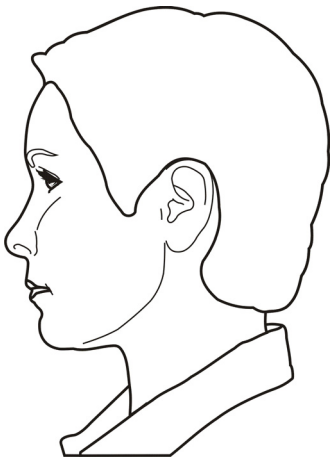


3.1.1 Cephalometric programs

Cephalometric pediatric lateral projection

Pediatric Lateral Cephalostat has an optimized image height (180 mm) that is used e.g. for pediatric patients but also adult patients to reduce the radiation dose. The pediatric lateral projection covers all the typical cephalostat landmarks from Nasion down to the spine and the starting point of the lateral scan is adjustable with both Standard and pediatric lateral cephalostat programs.

Exposure settings for cephalometric pediatric lateral program				
100 VAC	81 kV/8 mA/10 s	85 kV/8 mA/12 s	90 kV/8 mA/16 s	90 kV/8 mA/20 s
230 VAC	85 kV/8 mA/10 s	90 kV/8 mA/12 s	90 kV/10 mA/ 16 s	90 kV/13 mA/ 20 s
Note! *Patient size adult (third from the left) is the default exposure setting.*				



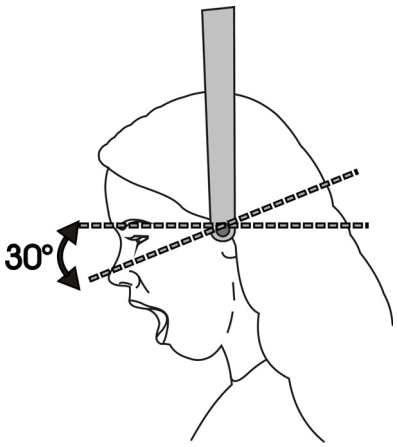
Cephalometric lateral projection

Lateral Cephalostat uses a full height image field (223 mm).

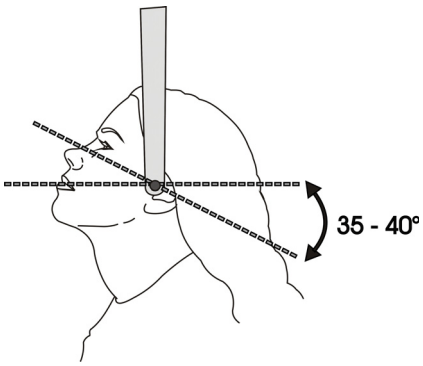
Exposure settings for cephalometric lateral program				
100 VAC	81 kV/8 mA/10 s	85 kV/8 mA/12 s	90 kV/8 mA/16 s	90 kV/8 mA/20 s
230 VAC	85 kV/8 mA/10 s	90 kV/8 mA/12 s	90 kV/10 mA/ 16 s	90 kV/13 mA/ 20 s
Note! *Patient size adult (third from the left) is the default exposure setting.*				

Cephalo posterior-anterior (PA) projection

Reverse towne projection

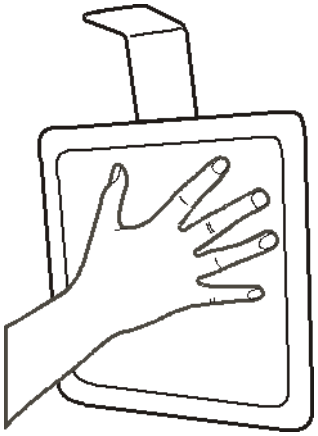


Waters view

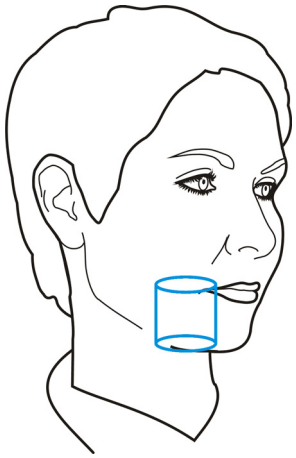


Exposure settings for cephalometric PA program				
100 VAC	81 kV/8 mA/10 s	85 kV/8 mA/12 s	90 kV/8 mA/16 s	90 kV/8 mA/20 s
230 VAC	85 kV/8 mA/10 s	90 kV/8 mA/12 s	90 kV/10 mA/ 16 s	90 kV/13 mA/ 20 s
Note! *Patient size adult (third from the left) is the default exposure setting.*				

Carpus view (Not available in USA and Canada)



Exposure settings for Carpus view program				
100 VAC	66 kV/3,2 mA/ 8 s	70 kV/3,2 mA/ 8 s	73 kV/3,2 mA/ 8 s	73 kV/6,3 mA/ 8 s
230 VAC	66 kV/3,2 mA/ 8 s	70 kV/3,2 mA/ 8 s	73 kV/3,2 mA/ 8 s	73 kV/6,3 mA/ 8 s
Note! *Patient size adult (third from the left) is the default exposure setting.*				

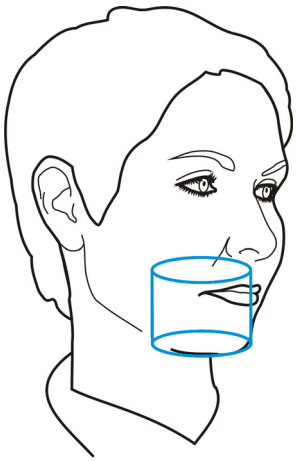


3.1.2 3D programs

61 x 41 mm FOV

High resolution (133µm voxel size)

Standard resolution (200µm voxel size)



Endo FOV 61 x 41 mm (height x diameter)

Program for optimized endodontic imaging.

Endo program (85µm voxel size)

61 x 78 mm FOV

Standard resolution or high resolution.

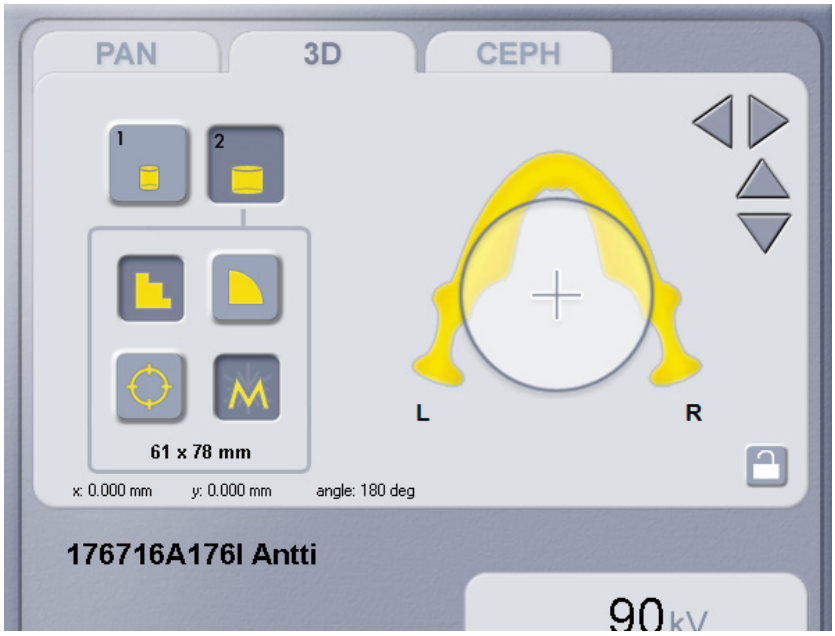
High resolution (200µm voxel size)

Standard resolution (300µm voxel size)

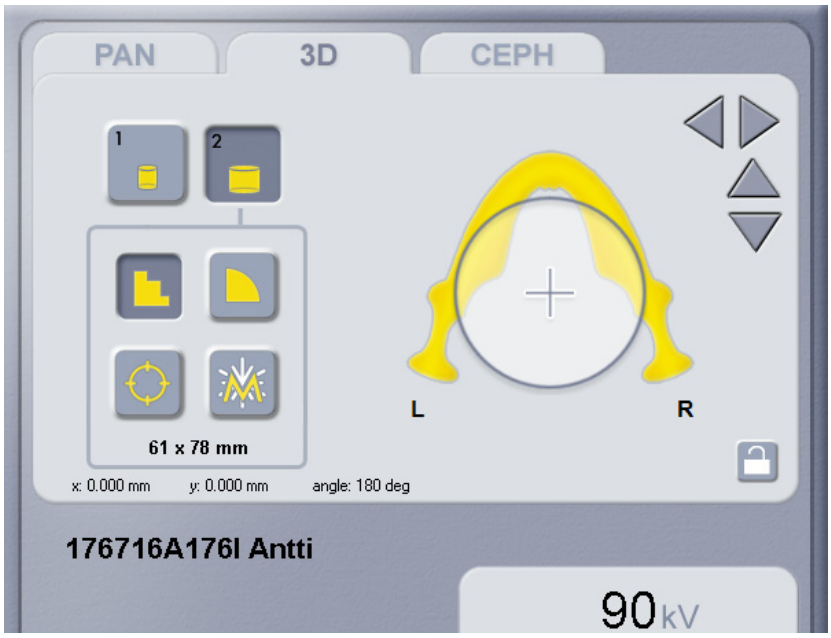
Exposure settings for 3D imaging (default values)				
Resolution	**FOV (h x w)**	**kV**	**mA**	**Exposure time**
Endo program	61 x 41 mm	90	10	6,1 s
High Res	61 x 41 mm	90	8	6,1 s
Std Res	61 x 41 mm	90	10	2,3 s
High Res	61 x 78 mm	90	6,3	13 s
Std Res	61 x 78 mm	90	10	4,9

3.1.3 MAR, Metal Artifact Reduction

MAR, Metal Artifact Reduction software can be used to reduce the effect of metals and other dense radiopaque objects on the 3D image. These create artifacts that are seen typically as stripes and shadows from the above-mentioned objects. To utilize MAR on a 3D image may have affect to image reconstruction time



MAR-button is ON. MAR-button becomes visible on the 3D modality.



MAR-button is OFF.

3.1.4 Exposure settings for 3D imaging

Exposure settings for 3D imaging							
Note! *Voltage settings is always 90kV with the unit 3D modality.*							
Resolution	**FOV (h x w)**	**Exposure time**	**Scanning time**	**Amount of projections**	**mA Low dose (DAP mGycm2)**	**mA High-quality (DAP mGycm2)**	**mA High-quality (DAP mGycm2)**
High Res	61 x 41 mm	6,1 s	10 s	608	6.3 mA (298)	8 mA (379)	13 mA (593)
Std Res	61 x 41 mm	2,3 s	10 s	230	8 mA (145)	10 mA (181)	13 mA (227)
High Res	61 x 78 mm	12,6 s	20 s	1260	5 mA (491)	6.3 mA (619)	10 mA (983)
Std Res	61 x 78 mm	4,9 s	20 s	460	8 mA (302)	10 mA (372)	13 mA (472)

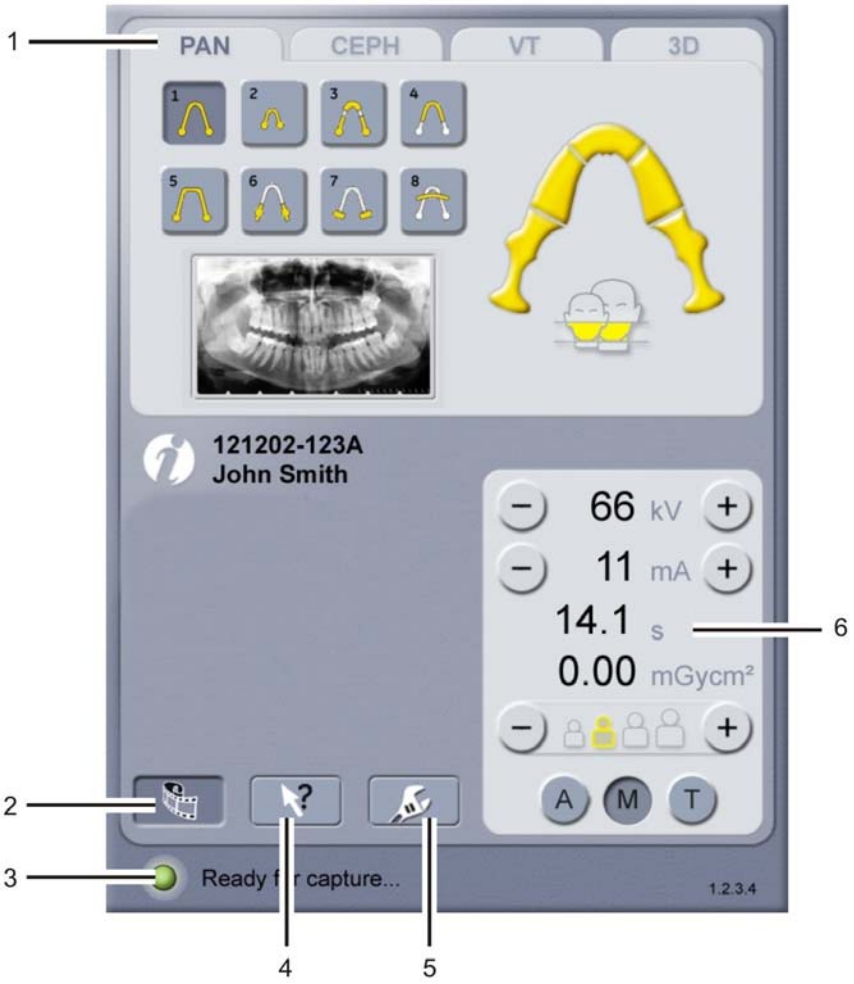
DAP values vary from unit to unit in relation to the x-ray tube output. Thus above values indicate average DAP values. In addition to these recommended values, there is a possibility to use the whole mA range if the user prefers.

Available mA ranges for each field of view sizes and resolution settings							
Resolution	**FOV (h x w)**	**4 mA**	**5 mA**	**6.3 mA**	**8 mA**	**10 mA**	**13 mA**
Endo program	61 x 41 mm	x	x	x	x	x	x
High Res	61 x 41 mm	x	x	x	x	x	x
Std Res	61 x 41 mm			x	x	x	x
High Res	61 x 78 mm	x	x	x	x	x	
Std Res	61 x 78 mm			x	x	x	x

Exposure settings for scout imaging (default values)				
Resolution	**FOV (h x w)**	**kV**	**mA**	**Scanning time**
Scout	61 x 41 mm	90	13	0,02 s
Scout	61 x 78 mm	90	13	0,04 s

4 Touch screen display

4.1 Main control panel



1. Modality / imaging program section
2. Status of the unit
3. Settings
4. End examination
5. Exposure settings

4.2 Modality section

Select the modality tab PAN, CEPH or 3D.

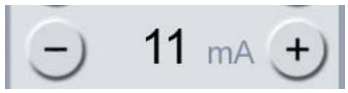
When panoramic modality is selected, a program specific dental arch is shown. This can be used for partial panoramic imaging.

Cephalometric programs have their own, program specific model heads and setting buttons for the start position of lateral scanning.

3D programs (two FOV sizes) have buttons for selecting low resolution, high resolution or scout image mode. The FOV for 3D imaging can be positioned on the XY-plane by selecting the center point of the FOV on the dental arch of the touch screen display. The FOV is positioned in the Z-direction by using the chin rest movement and positioning lights.

4.2.1 Exposure indicators and settings

kV value



mA value

Exposure time

Dose value

Patient size settings
(Child, juvenile,
small adult, large adult)

Manual dose rate control

Test mode

Exposure Indicator

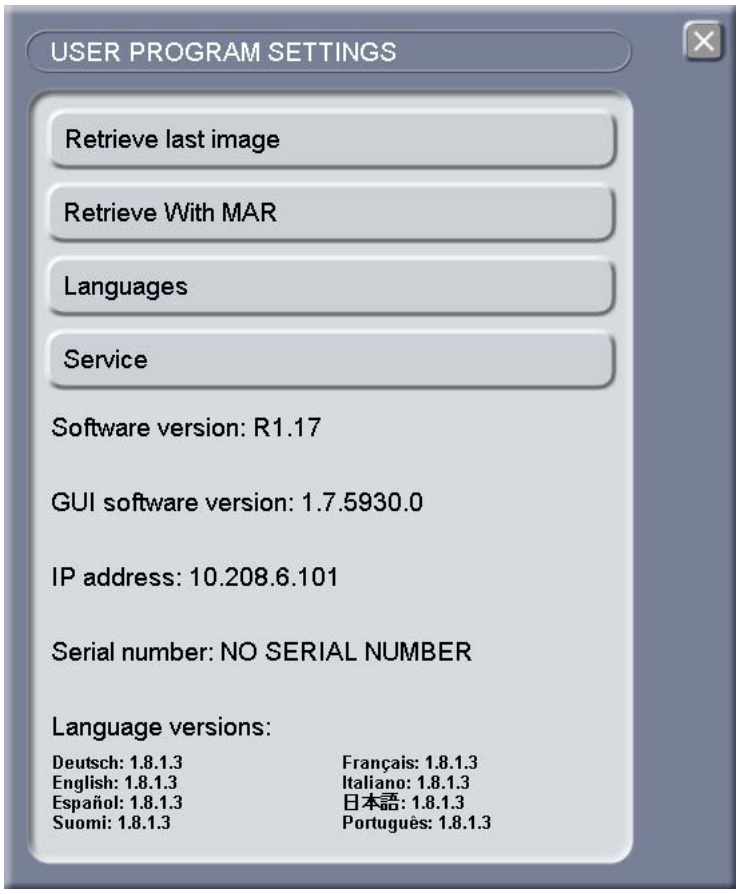
4.3 Status section

Status field shows when the unit is ready for capturing or any trouble occurs. Green, yellow and blue color indicate the status in question.

Ready for imaging

4.4 Other sections

General settings



- Retrieve Last Image
  - Use this to retrieve the last image from the device memory e.g. after a system crash

- Retrieve With MAR
  - After taking a 3D image with MAR either on or off, image can be re-reconstructed with different setting by selecting either “Retrieve last image” or “Retrieve With MAR™” from the general settings on the touch screen. If reconstruction with MAR is unavailable for the last captured image, e.g. last taken image is cephalometric, “Retrieve With MAR”-button will not be visible.

  NOTE! *Only the last taken x-ray image is saved in the unit until the power is switched off. This image data is used in the retrieve procedure.*

- Languages
  - Use this to select language on the touchscreen

- Service
  - Use this to reach the programs for periodical maintenance

5 Using the unit

5.1 Attaching and removing the sensor

Note! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

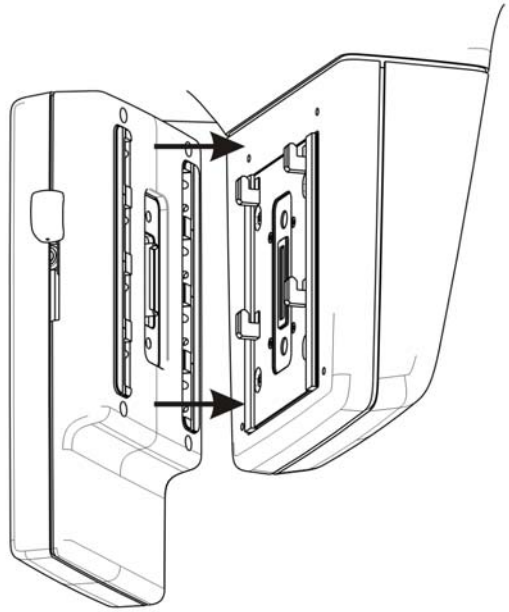
Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.

WARNING!

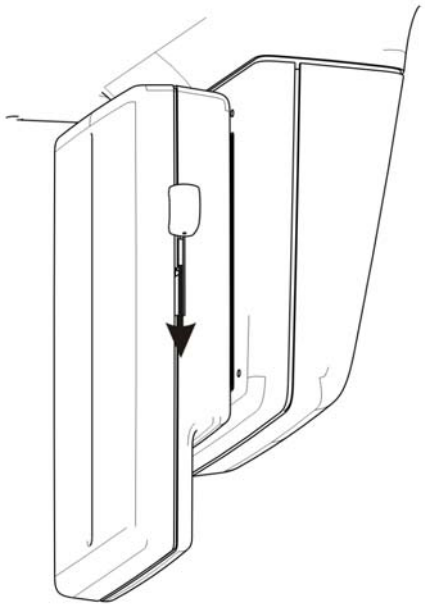
Handle the sensor with care as instructed in this manual. The sensor must not be dropped or exposed to impacts. A shock indicator inside the sensor shows if the sensor has been exposed to excess impact.

5.1.1 Attaching the sensor

1. Insert the four slots on the rear of the sensor, into the four hooks in the sensor holder.

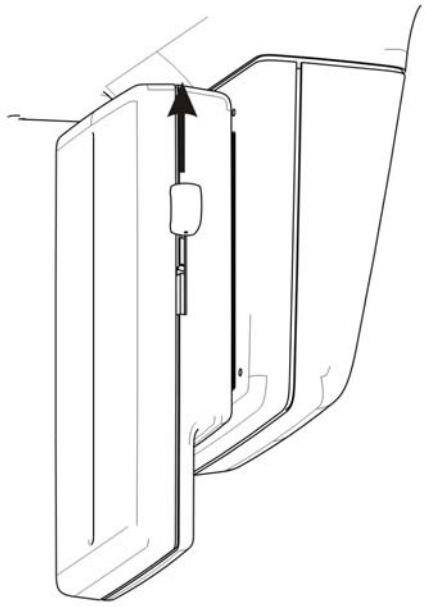


2. Slide the sensor downwards until it stops and then slide the locking knob down on the side of the sensor to lock the sensor in position.



5.1.2 Removing the sensor

1. Slide the locking knob upwards on the side of the sensor to unlock the sensor.



2. Slide the sensor up and remove it.

5.2 Preparing the system

1. Switch on the unit and the PC.
2. **PC:** Start CLINIVIEW™ software (or 3rd party application).
3. **PC:** Open a new or existing patient or select a patient from the worklist. See the user's guide supplied with the dental imaging program.

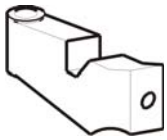
5.3 Panoramic exposures

- Standard
- Pediatric
- Ortho Zone
- Orthogonal
- Wide arch
- Bitewing
- Ortho TMJ axially corrected lateral projection
- TMJ PA projection
- Maxillary sinus view

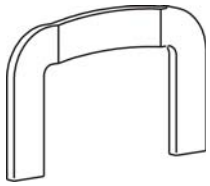
5.3.1 Positioning devices

Bite fork with the bite block

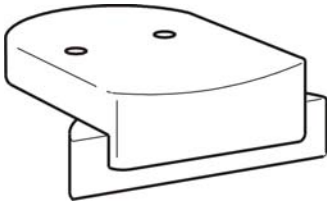
Bite fork with the edentulous bite positioner



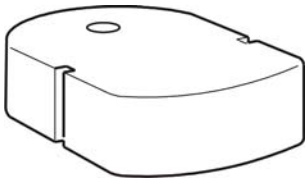
Chin support for edentulous patients



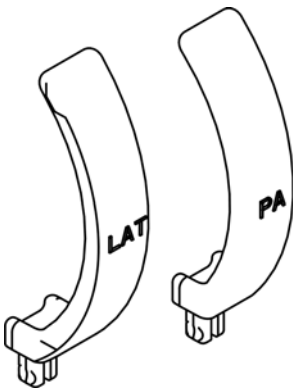
Sinus rest



Chin rest

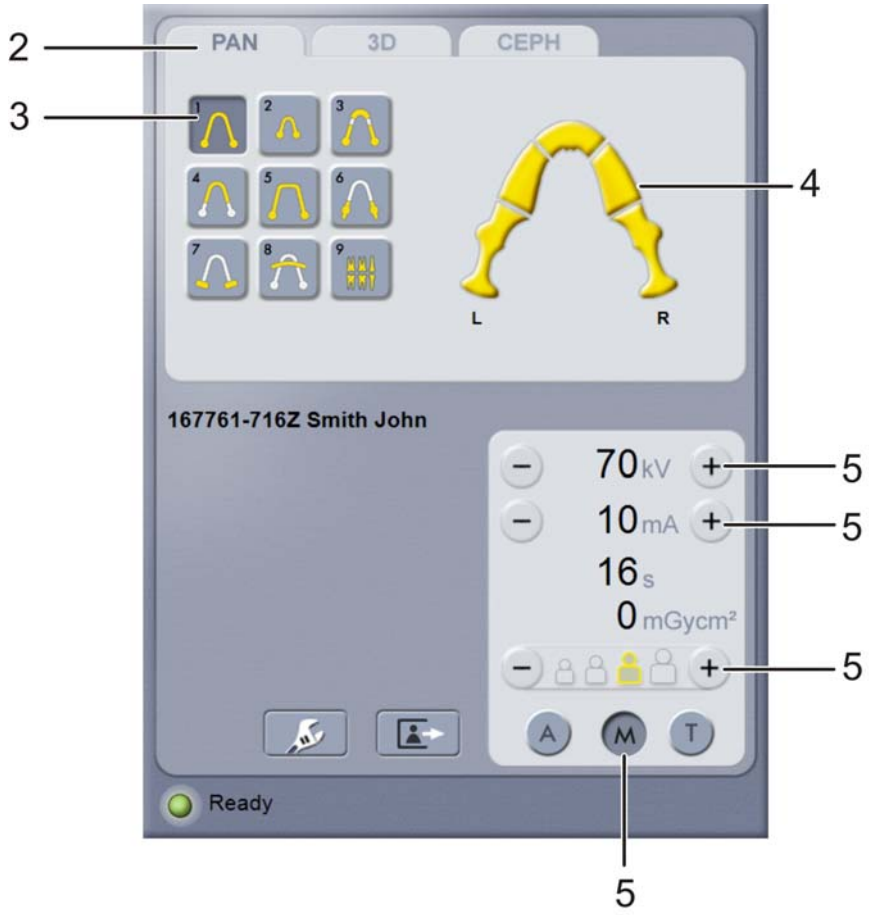


TMJ nose support



5.3.2 General instructions

1. **PC:** Click **Image Capture**



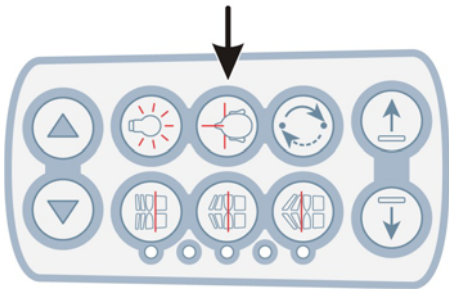
2. Select PAN tab.

3. Select the imaging program.

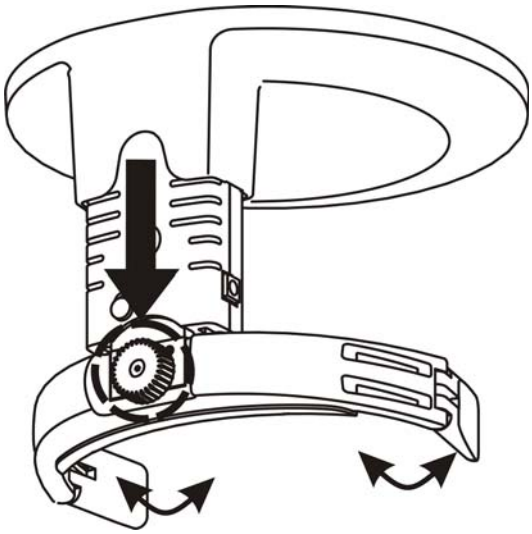
4. Any section of the tooth arch can be selected for the partial panoramic imaging to reduce the radiation.

5. Select the Manual mode.
   Set the kV and mA, or select the patient size (child, juvenile, adult, large adult).

6. Press the patient positioning button to rotate the unit to ‘patient in’ position.



7. Open the temple supports.



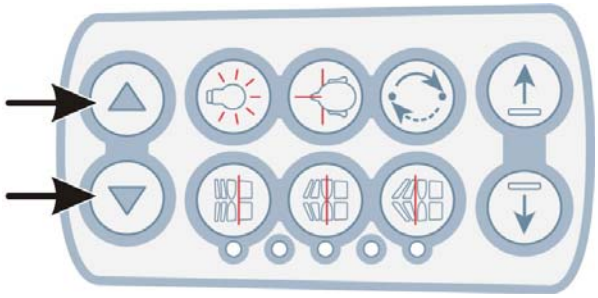
8. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins. Place a protective lead apron on the patient.

5.3.3 Patient positioning

5.3.3.1 Panoramic exposure

1. Insert the sinus rest, chin rest and bite fork with the bite block. Place the disposable covers.
   Note! *Use a new disposable cover for every patient*.

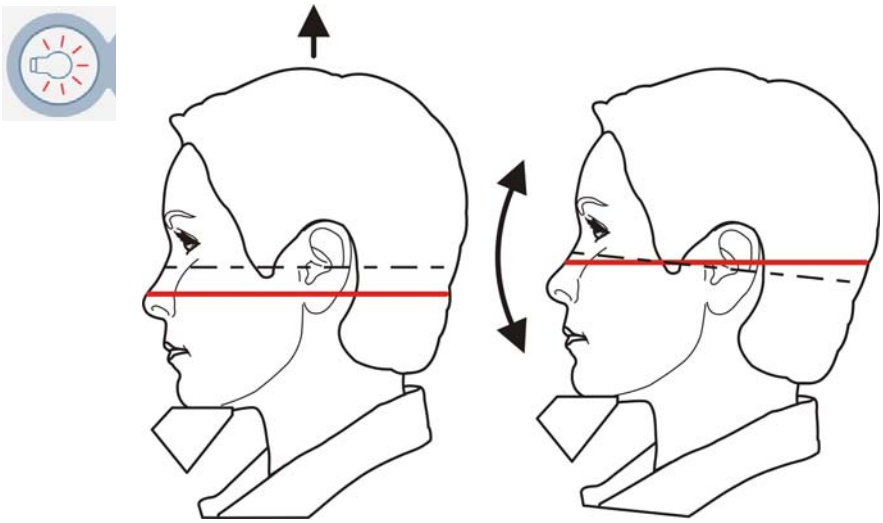
2. Adjust the unit height



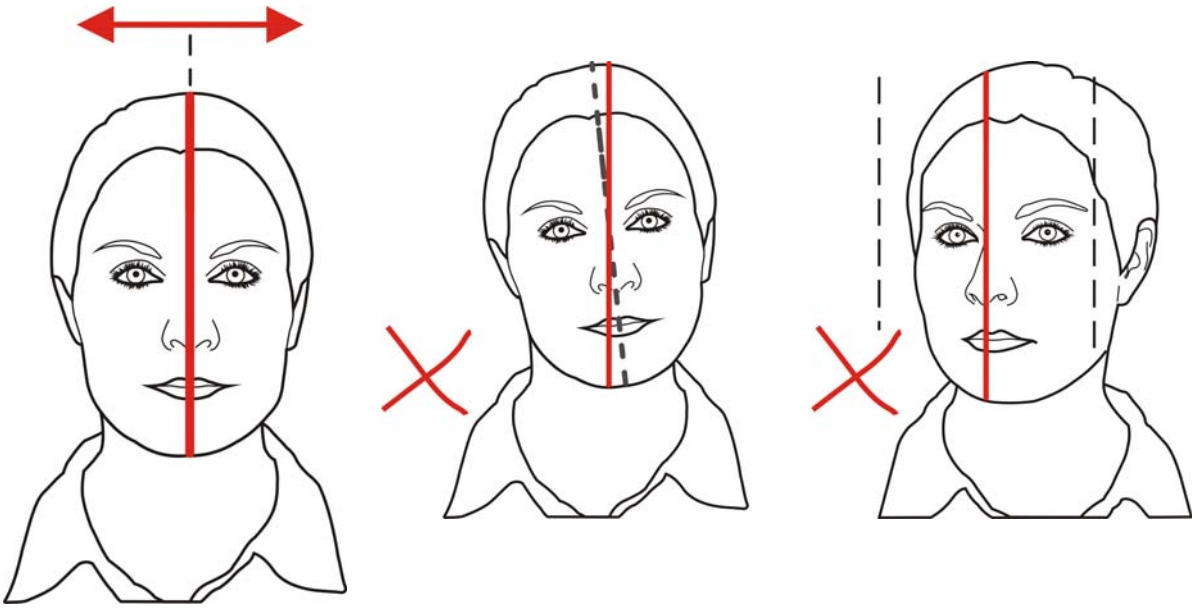
3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Exposure can be taken also in sitting position. Ask the patient to take grip on the handles and bite on the bite block. Use the edentulous bite positioner or the chin support for an edentulous patient.

4. Ask the patient to take one step forward to straighten the spinal column. Patient is slightly leaning backwards during the imaging.

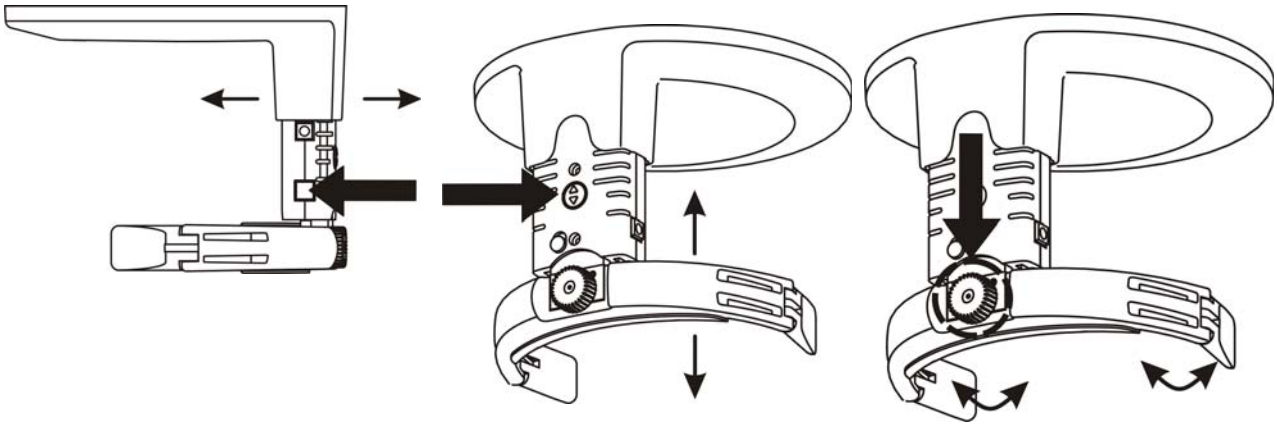
5. Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.



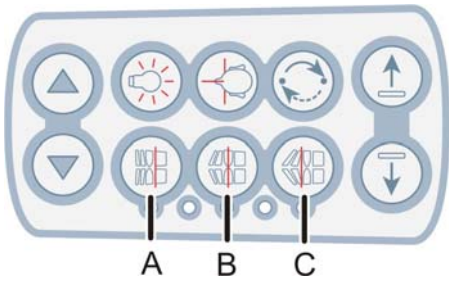
6. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.
Make sure the patient's head is not turned or tilted.



7. Move the head support against the patient's forehead. Adjust the height. Close the temple supports.



8. Check the position of the image layer light. If it is not on middle of the maxillary canine (or base of the nose, if edentulous), adjust the image layer.



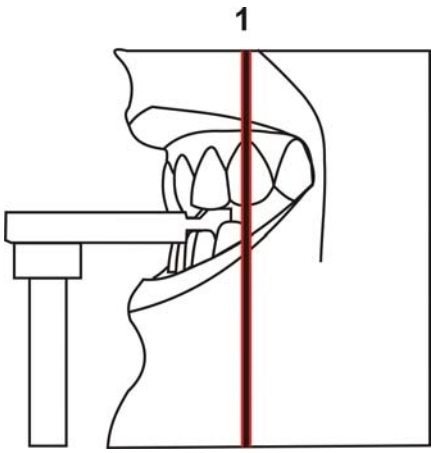


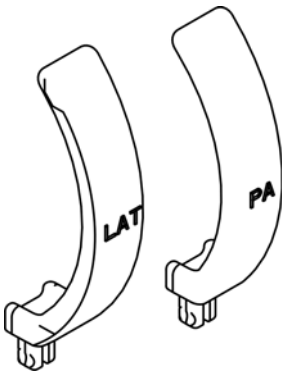
Image layer adjustment buttons:

A) Retrusion
B) Normal occlusion (default)
C) Protrusion

9. Ask the patient to press their tongue against the roof of their mouth, **swallow** and remain still for the duration of the exposure.

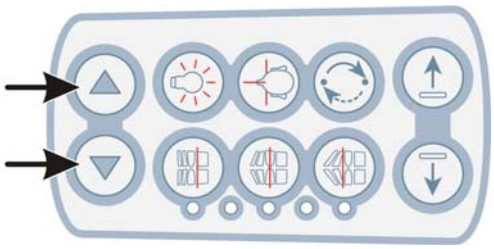
5.3.3.2 TMJ exposure

Nose support



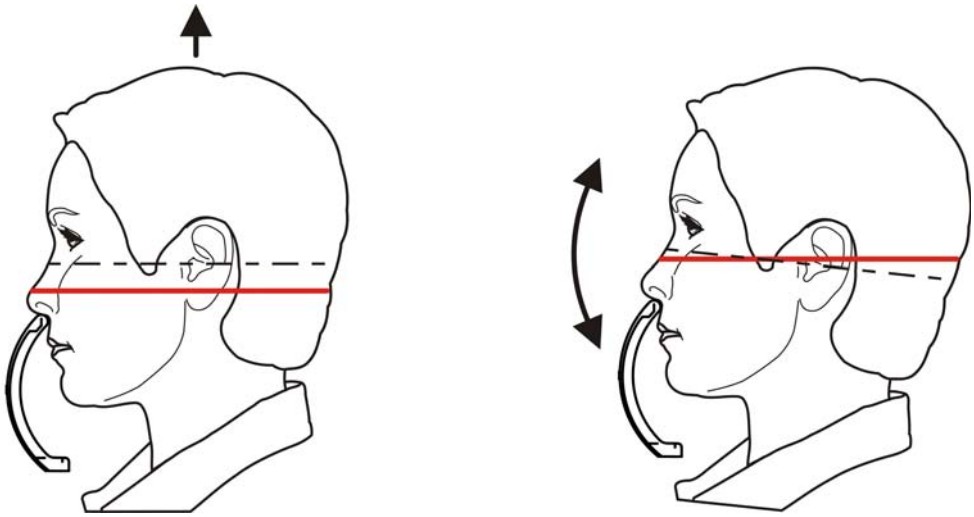
1. Insert the required positioning devices, including the TMJ nose support. Place the disposable covers.
   Note! *Use a new disposable cover for every patient.*

2. Adjust the unit height

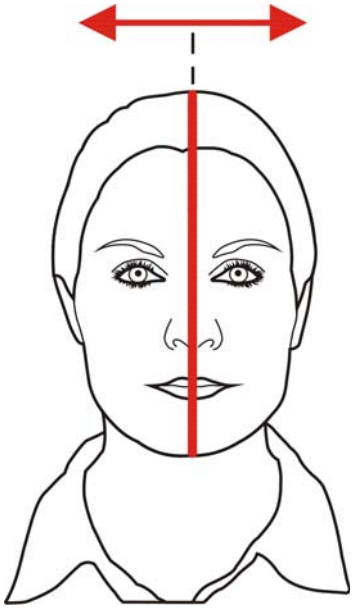


3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Ask the patient to take grip on the handles and set the nose against the TMJ nose support.

4. Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.



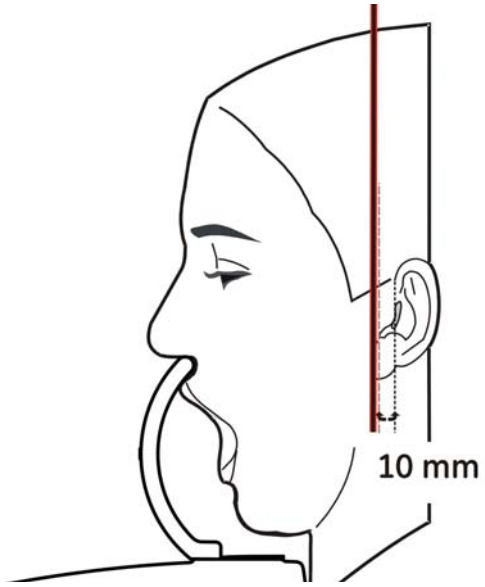
5. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient’s head.

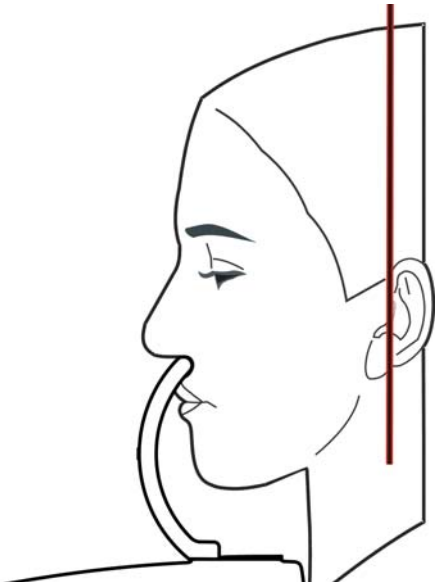


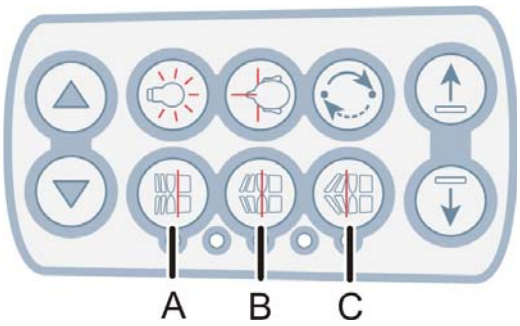
6. Move the head support against the patient’s forehead. Adjust the height. Close the temple supports.

7. Adjust the position of the TMJ light until it aligns in the middle of condyle.

Note! *The condyle moves forward by approximately 10 mm when the mouth is opened.*







TMJ light adjustment buttons:

A) Forward (towards the mirror)

B) Reset

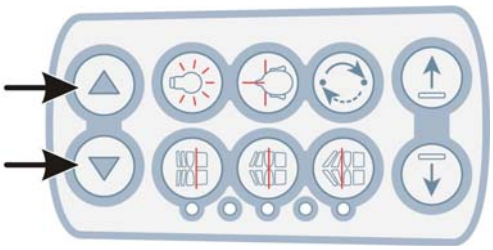
C) Backward (away from the mirror)

5.3.3.3 Maxillary Sinus exposure

1. Insert the required positioning devices, bite fork with the bite block on the sinus rest. Place the disposable covers.

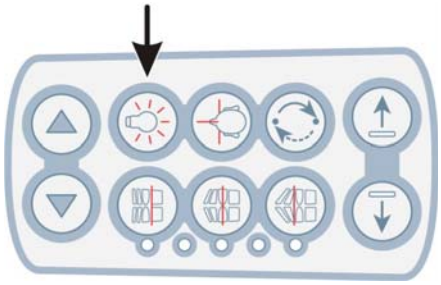
   Note! *Use a new disposable cover for every patient.*

2. Adjust the unit height

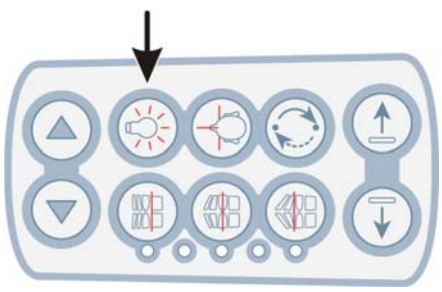


3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Ask the patient to take grip on the handles and bite on the bite block.

4. Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.



5. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.



6. Move the head support against the patient's forehead. Adjust the height. Close the temple supports.

7. Adjust the position of the image layer as necessary. The image layer is 18 mm posterior compared to standard panoramic procedure.

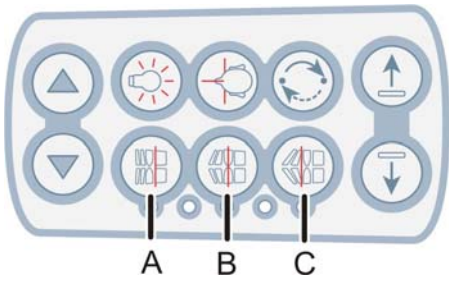


Image layer adjustment buttons:

A 10 mm anterior

B Center

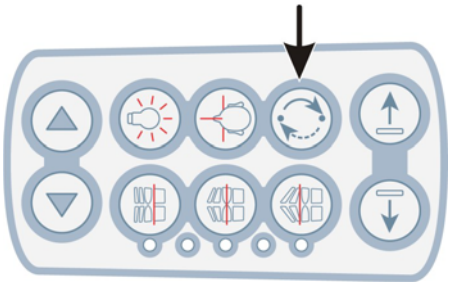
C 10 mm posterior

8. Ask the patient to press their tongue against the roof of their mouth and remain still for the duration of the exposure.

5.3.4 Taking the exposure

1. Press **Start position**. Check the patient positioning.

Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.



Note! *In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray beam. Operator should maintain visible contact with the patient and technique factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.*

Note! *If the patient is nervous, or a child, you can demonstrate how the unit works to reassure them. Press the T (Test mode) button and then press and hold the exposure button. The unit will complete an exposure cycle without generating x-rays.*

2. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the touch screen display appears.

The unit rotates around the patient's head and stops. When the rotating unit stops, the exposure has been taken.

3. After the exposure the rotating unit is in ‘patient out’ position, if the exposure switch has been pressed until all movements have stopped. Release temple supports. Guide the patient out. Remove disposable covers and disinfect the unit.

5.3.5 Multilayer Selection

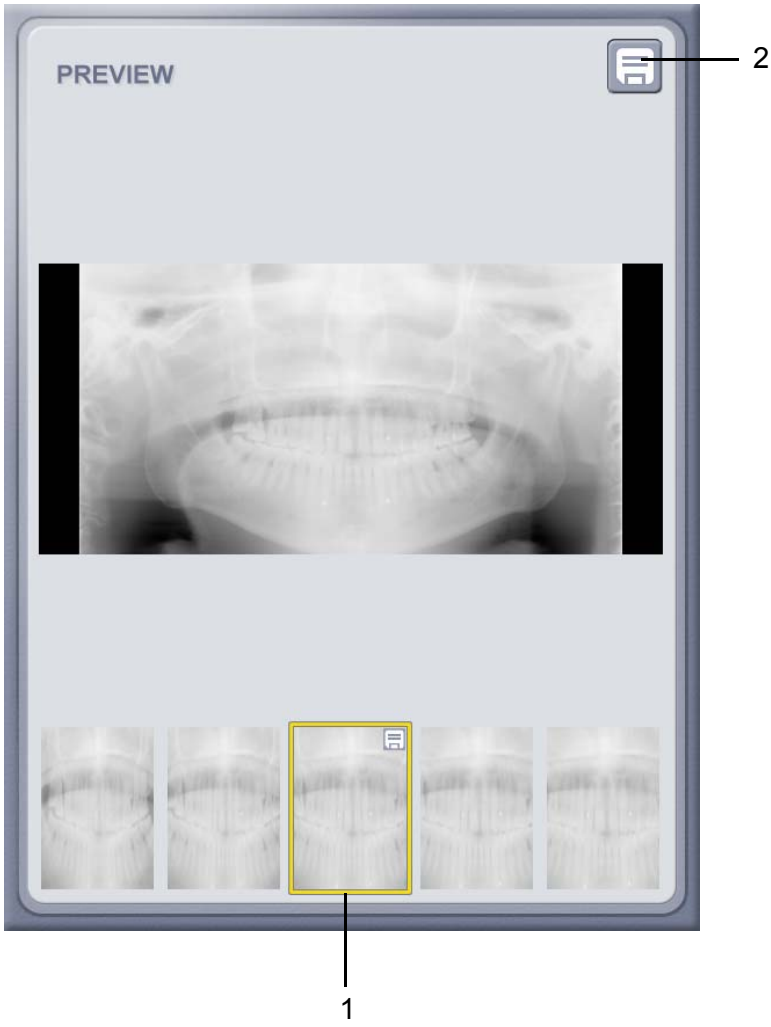
For maximum image clarity and sharpness, the position of the focal trough may be adjusted after exposure. Five pre-adjusted images are calculated and displayed on the touch screen. In the midmost image no adjustment is applied, i.e. the focal through is located exactly at the layer laser position. To the left of this are images where the focal through is adjusted towards the patients neck (posterior). To the right are images where the focal through is adjusted towards the patients lips (anterior). The difference in adjustment between the images is 3 mm.

1. The touch screen shows one of the thumbnail images as magnified. To select which image is shown, press the corresponding thumbnail image in the lower part of the screen. Once shown as magnified, an image may be marked for saving by again pressing the thumbnail. An save indication icon is shown in the upper right of the thumbnail image. Repeat this process for all images of interest.

2. Press the save button in the upper right of the screen. The image(s) marked for saving will be sent to the workstation.

3. **PC:** The image(s) can be examined using the Cliview software. See CLINIVIEW™ user manual for details.

   Note! *The X-ray unit may be configured to automatically select either the unadjusted (midmost) image or send all images to the workstation. In such cases, the selection process described above is bypassed.*



1. Preview selection
2. Save button

■

5.4 Cephalometric exposures

- Pediatric lateral projection
- Lateral projection
- PA projection
- Reverse towne projection
- Waters view
- Carpus view (Not available in USA and Canada)

WARNING!

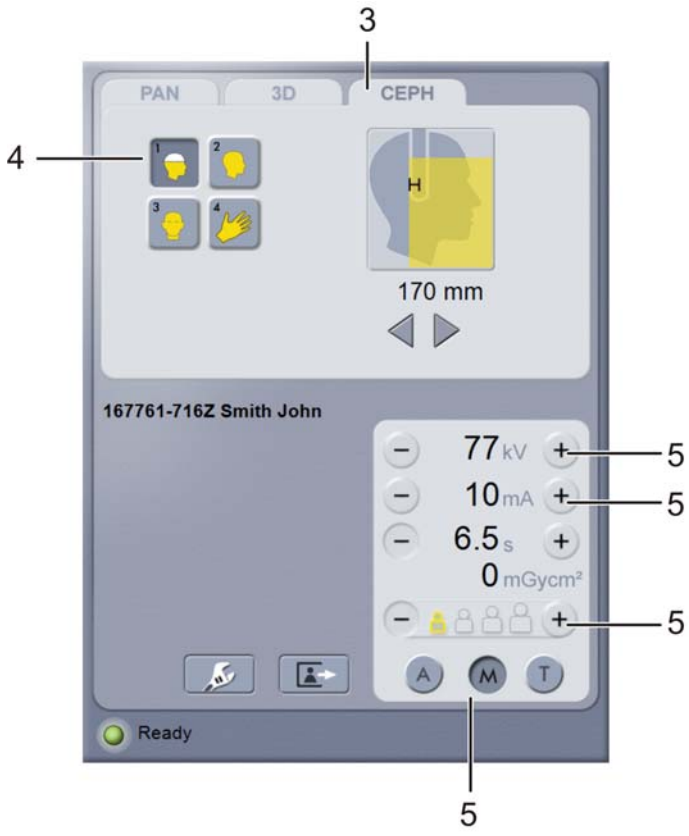
Remove all calibration tools, Pan and 3D patient positioning accessories before taking any cephalomateric exposures!

5.4.1 General instructions

1. Move the ceph sensor to the ceph sensor holder.

2. **PC:** Click **Image Capture**.

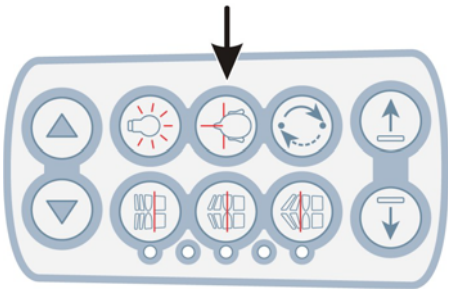
3. Select CEPH tab.



4. Select the imaging program.

5. Select the Manual mode (Default).
   Set the kV and mA or
   select the patient size
   (child, juvenile, adult, large adult).

6. Press the patient positioning button to drive the unit to ‘patient in’ position.



7. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins. Place a protective lead apron on the patient.

5.4.2 Patient positioning

5.4.2.1 Pediatric lateral and Lateral projection

1. Unlock the lever and turn the ear rods to the lateral projection position. Lock the position. Tilt the nasion support aside. Place the disposable covers.

Unlock first the lever, turn the ear rods and lock the lever again.

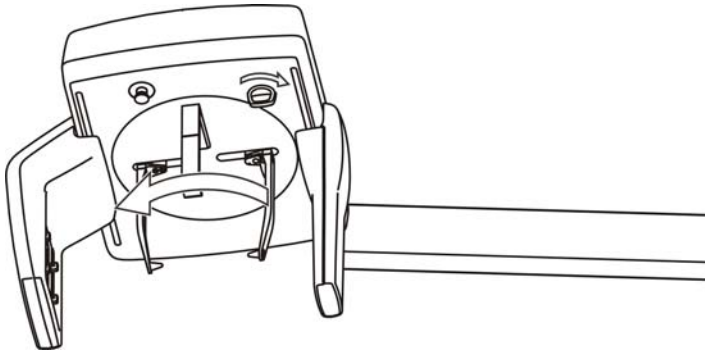
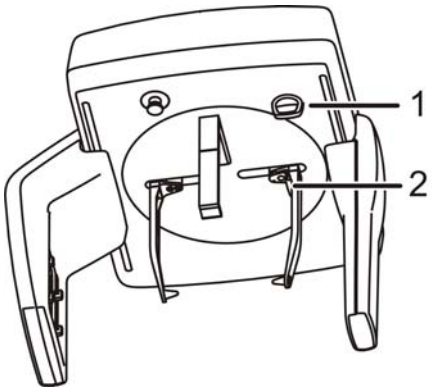
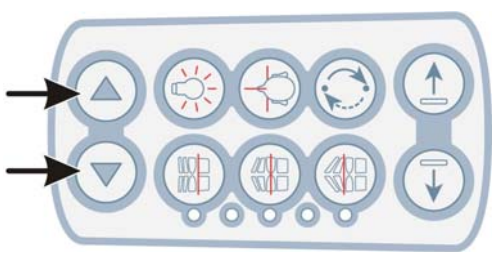


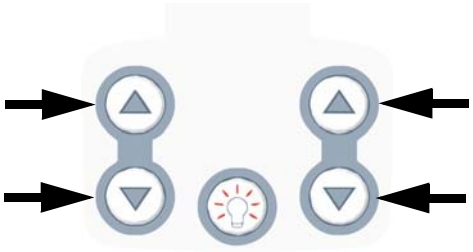
Figure 1.1 Locking lever (1), ear holder brake (2)



Note! *Use a new disposable cover for every patient.*

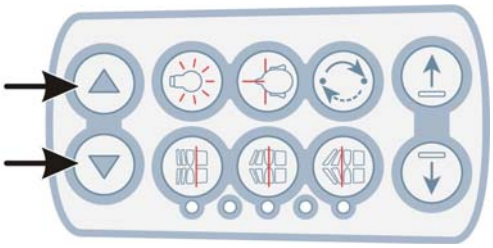
2. Adjust the unit height.

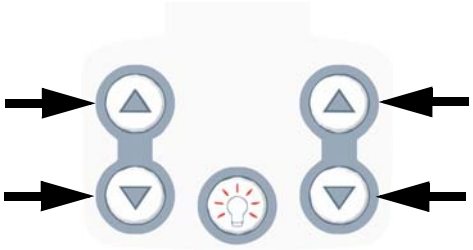




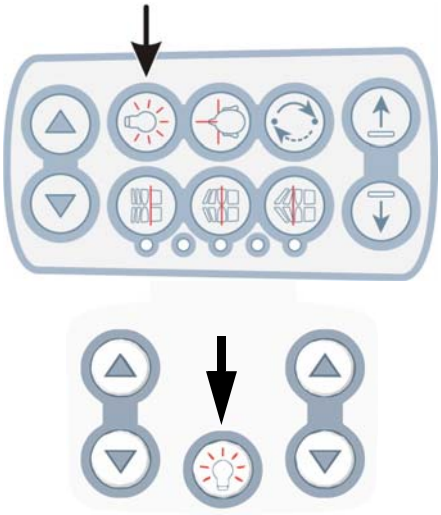
3. Guide the patient to the unit. Instruct the patient to stand as straight and tall as possible under the cephalostat head. Slide the ear rods towards to patient's ears. Tall patients can also sit on a chair.

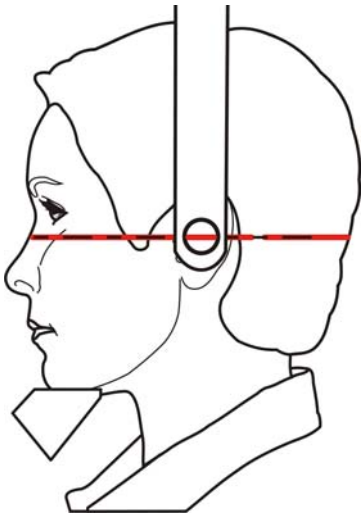
4. Adjust the unit height to get the Frankfort-Horizontal plane (FH) laser light passing over the orbita porion.





Note!
The shown laser line is a horizontal reference line.





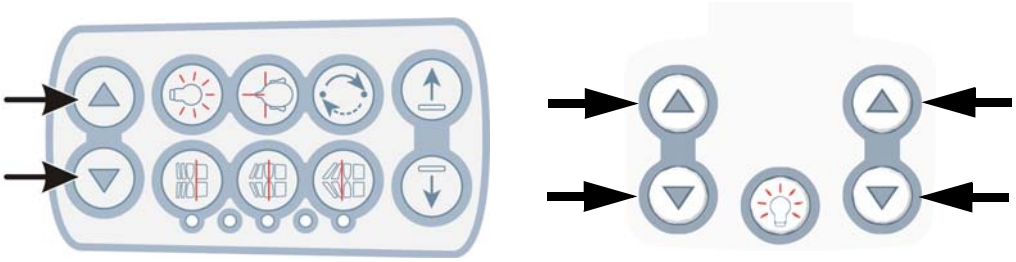
5. Tilt the nasion support down and slide it towards patient's nasion.

5.4.2.2 PA projection

1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside. Place the disposable covers.

   Note! Use a new disposable cover for every patient.

2. Adjust the unit height.



3. Guide the patient to the unit facing the sensor. Instruct the patient to stand as straight and tall as possible under the cephalostat head. Slide the ear rods towards patient's ears. Tall patients can also sit on a chair.

Figure 1.2 Unlock first the lever, turn the ear rods and lock the lever again.

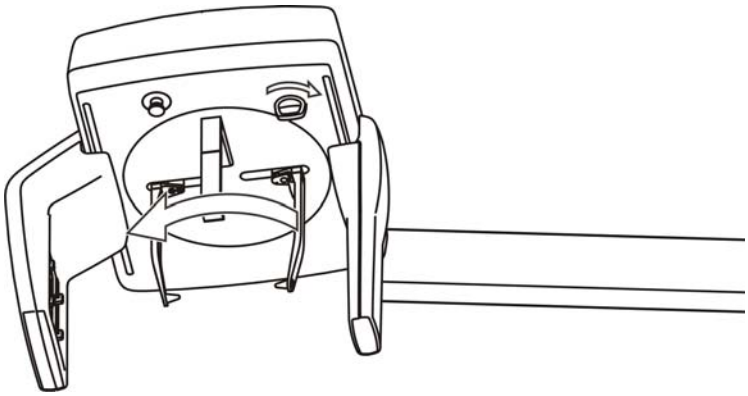
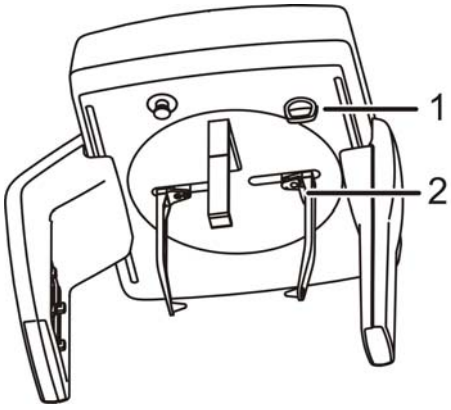


Figure 1.3 Locking lever (1), ear holder brake (2)



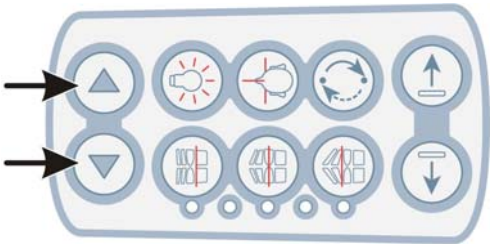
Note! *Use a new disposable cover for every patient.*

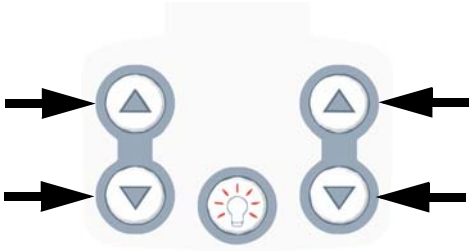
5.4.2.3 Reverse towne projection

1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside. Place the disposable covers.

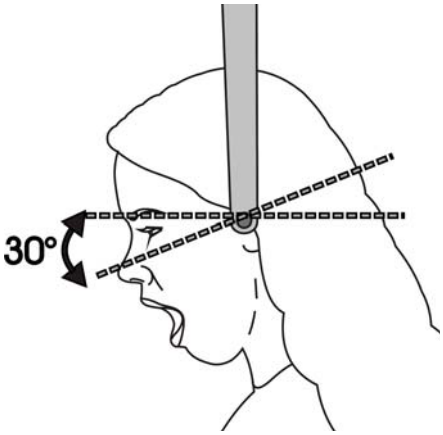
   Note! Use a new disposable cover for every patient.

2. Adjust the unit height.





3. Guide the patient to the unit. Instruct the patient to stand as straight and tall as possible under the cephalostat head.



4. Turn the head ventral as reference to the canthomeatal line about 30° below the horizontal plane.

5. Slide the ear rods towards patient's ears.

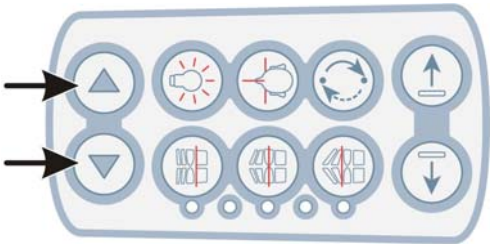
6. Ask the patient open mouth maximally.

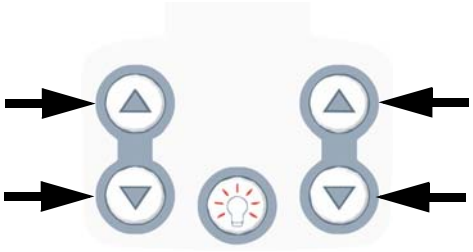
5.4.2.4 Waters view

1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside. Place the disposable covers.

   Note! Use a new disposable cover for every patient.

2. Adjust the unit height.



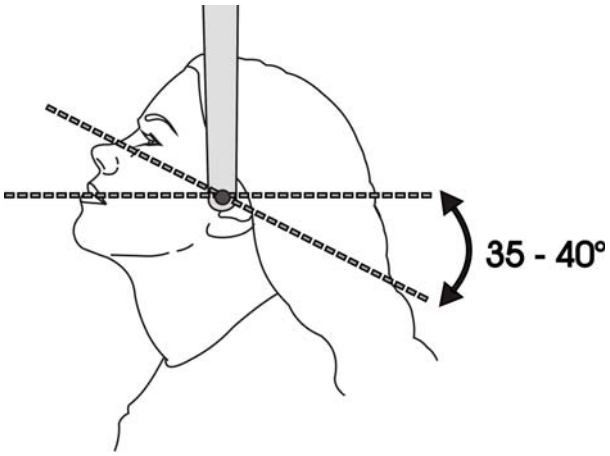


3. Guide the patient to the unit. Instruct the patient to stand as straight and tall as possible under the cephalostat head.

4. Turn the head dorsal as reference to the canthomeatal line about 35-40° above the horizontal plane.

5. Slide the ear rods towards patient's ears.

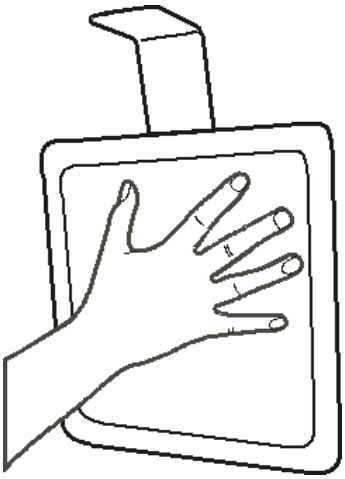
6. Ask the patient open or close mouth.



5.4.2.5 Carpus view (Not available in USA and Canada)

CAUTION!

Before taking Carpus image make sure this imaging method is approved by local authorities of your country.



1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside. Place the carpus holder to the nasion support holder.
2. Adjust the unit height if needed.
3. Ask the patient to remove rings and metal objects and to place hand on the carpus holder.

5.4.2.6 Taking the exposure

1. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.

2. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the touch screen display appears.

3. Release the ear rods and guide the patient out. Remove disposable covers and disinfect the unit.

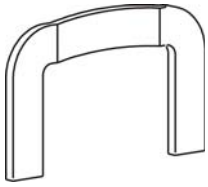
4. **PC:** The image can be examined using the CLINIVIEW™ software. See CLINIVIEW™ user manual.

Note! *In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray beam. Operator should maintain visible contact with the patient and technique factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.*

5.5 3D exposures

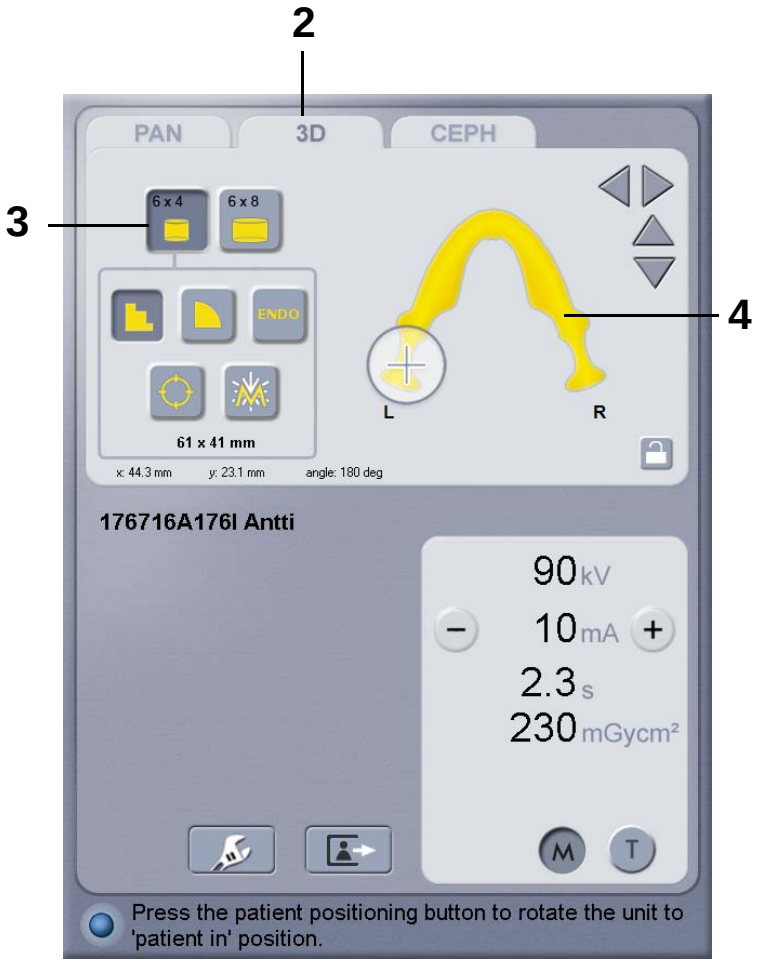
5.5.1 Positioning devices

Chin support



5.5.2 General instructions

1. PC: Click **Image Capture**.
2. Select the 3D modality tab.

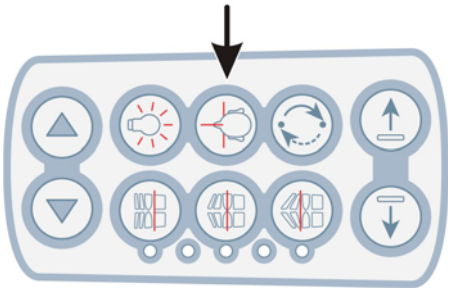


3. Select the Field Of View (FOV):
   61 x 41 mm FOV (Program 1)
   61 x 78 mm FOV (Program 2)

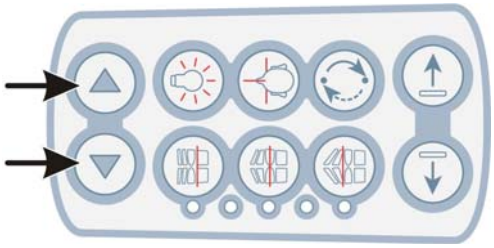
4. Move the FOV cursor on the area of interest. For precise adjustment the arrow keys can be used. The 3D FOV is positioned more accurately by using the scout image mode. The area of interest can be adjusted on the touch screen display after the scout image has been taken.

5. Lock the position by pressing the lock key. Use the same key for unlocking if the position needs to be changed.

6. Press the patient positioning button to rotate the unit to ‘patient in’ position



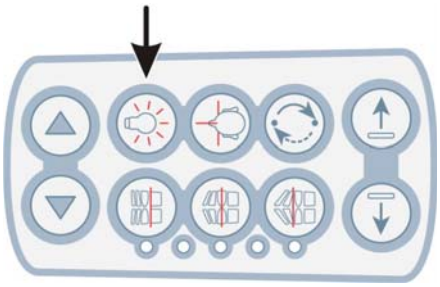
7. Adjust the unit height.

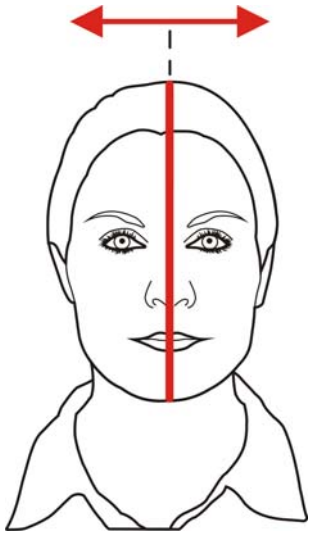


8. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins.

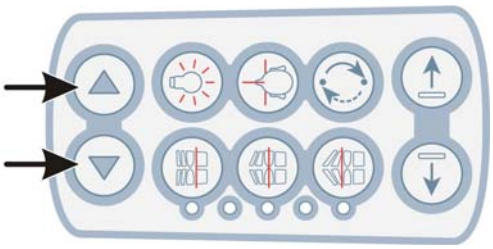
9. Guide patient to the unit. Instruct patient to stand as straight and tall as possible next to the unit. Patient can also be imaged in sitting position. Ask the patient to take grip on the handles and place chin on the chin rest.

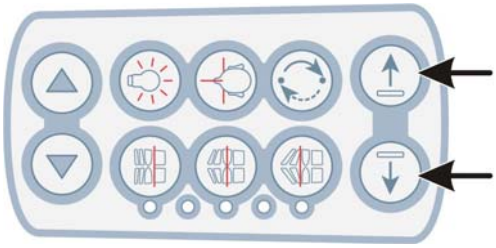
10. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.

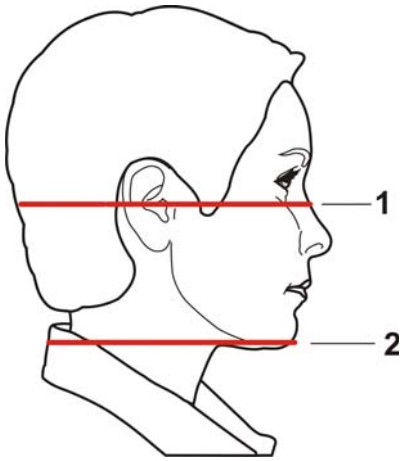




11. Adjust the unit height and chin rest height to get the area of interest between the top and bottom FOV lights. Position the patient so that the occlusal plane is horizontal.

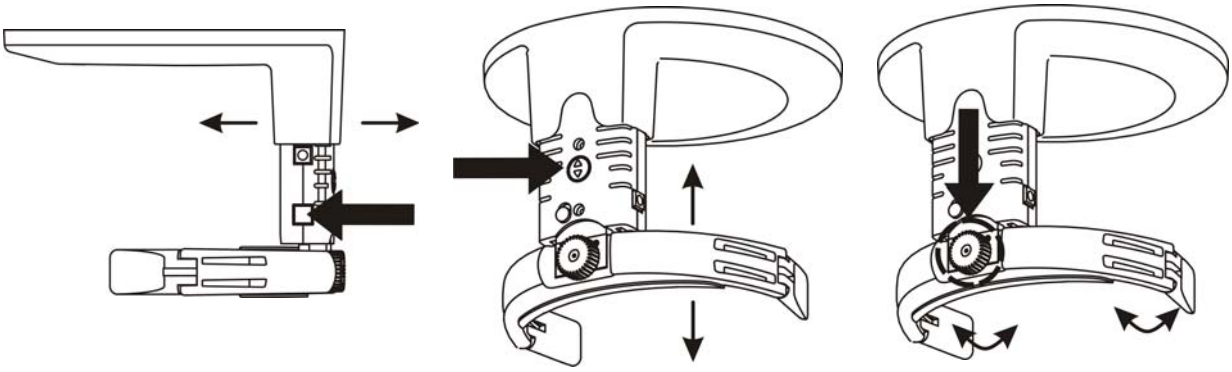






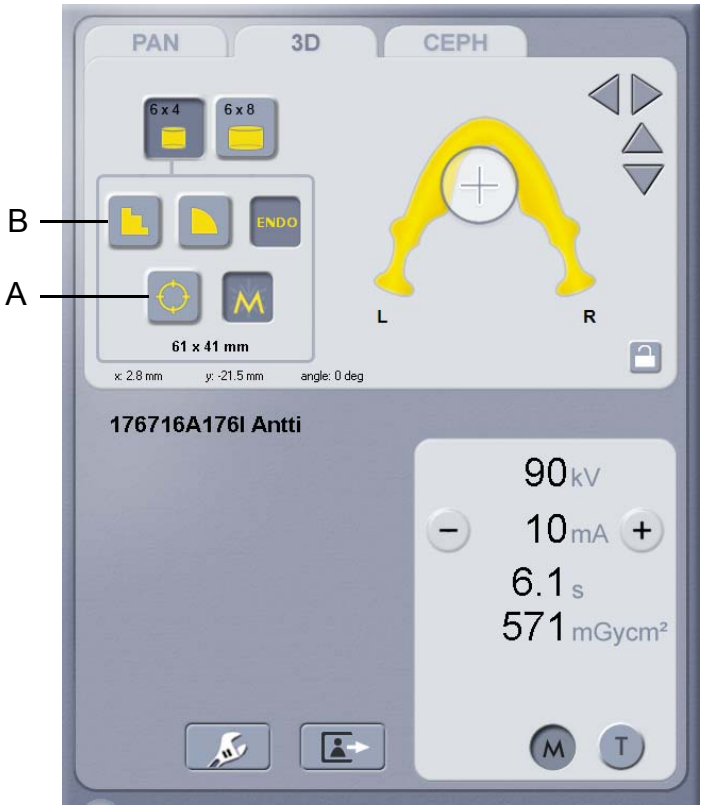
1. H light, top of FOV
2. H light, bottom of FOV

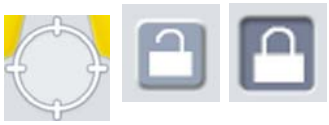
12. Move the head support against the patient's forehead. Adjust the height. Close the temple supports.



13. Select

A the Scout image
or
B the Standard or high resolution 3D image





14. Move the FOV cursor on the area of interest. For precise adjustment the arrow keys can be used. Lock the position by pressing the lock key. Use the same key for unlocking if the position needs to be changed.

5.5.3 Scout image

1. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the touch screen display appears.

2. Scout preview image appears to the touch screen display.

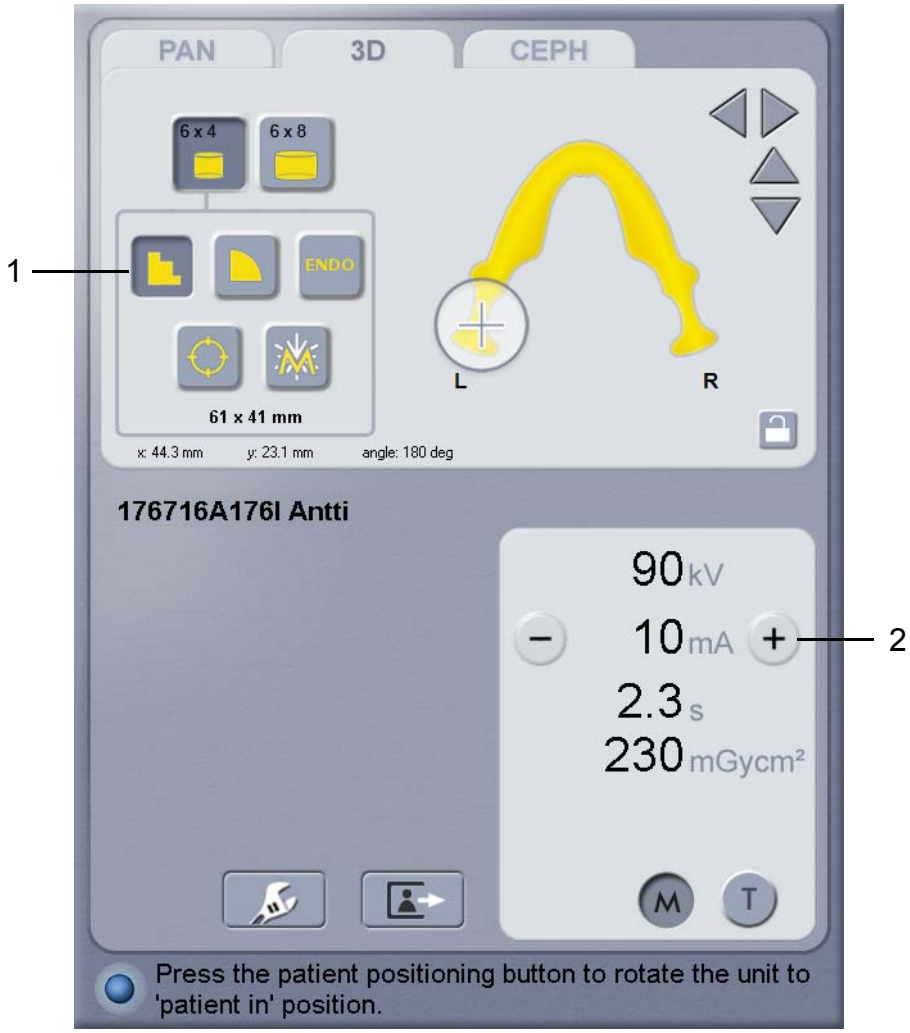
3. Fine adjust scout position using the side arrow keys. Press the right upper corner icon to continue.

4. Take a new scout or
save current and continue to 3D image.

5.5.4 3D image

1. Select the Standard (A), high resolution (B) or endo program (C). Endo program is only for 61 x 41 mm FOV.

A B C



2. Select mA.

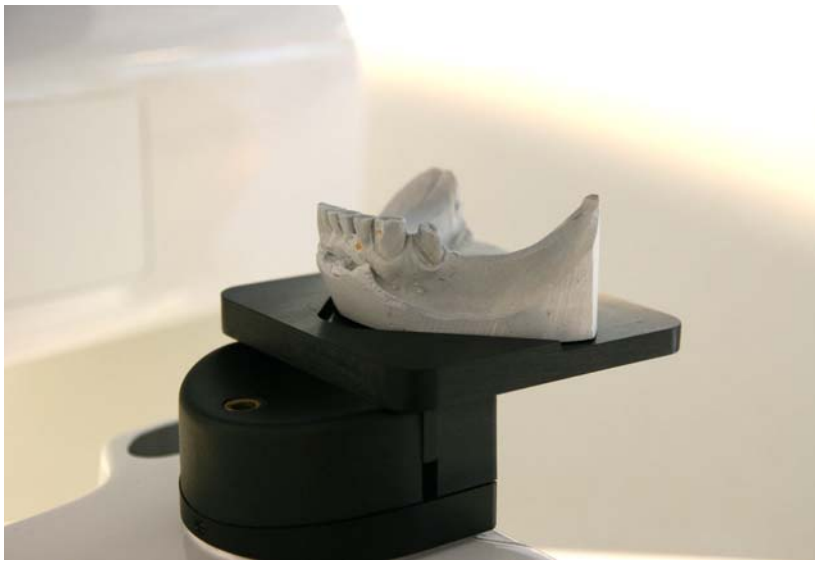
3. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the touch screen display appears.

4. Select **MAR** ON or OFF based on your estimation of the need. See chapter 3.4.1. Instructions for using MAR.

5.5.4.1 Stone model and radiographic guide scan

For scanning of stone models and radiographic guides, a positioning plate is available for the system.

1. Scan the patient with an open bite by securing the bite with cotton pads.
2. Install positioning plate. Position stone model.



Note! *It is recommended to use a sponge or a foam under radiographic guide during the scan.*

3. Take scout image with default values. Correct position if needed.

4. Select same resolution and parameters as in patient scan.

Note! More detailed instructions in OP300 Quick Guide Stone model and radiographic guide scan protocol.

5.6 Warnings and error messages

The unit responds to error situations by showing a dialog box containing an error code and descriptive text on the touch screen.

When an error code appears on the display the unit will stop working and cannot be operated while the error code is on the display. In less severe cases a warning message will be displayed, leaving the unit operable.

5.6.1 Acknowledging errors

Most errors may be acknowledged by closing the dialog box the error is reported in. Some errors require the unit to be rebooted. If such an error occurs, or if the unit fails to operate as described in the user's manual, switch the unit off, wait a few seconds and switch the unit on again.

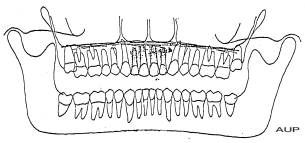
5.6.2 Image transfer errors

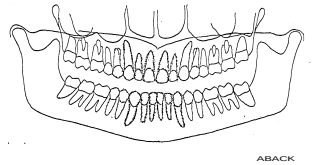
If an image is not transferred successfully to the PC, close and then reopen the dental imaging software and/or restart the PC. DO NOT restart the unit as this will erase any image that is stored in the unit memory and this retrievable image will be lost. If restarting the PC and/or restarting the dental imaging software does not allow you to retrieve the images, contact technical support without restarting the unit.

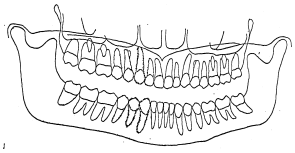
6 Troubleshooting

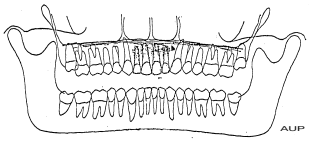
High quality images with sharp contrast and good detail provide optimum diagnostic information. Images with less quality are usually the result of one or more common problems.

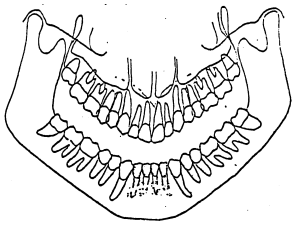
6.1 Patient positioning

Problem	Possible cause	Remedy
Incisors and canines narrow and unsharp. Overshadow in molar and premolar areas. Rows of teeth are compressed. 	1. Occlusal correction of focal trough set too far posterior 2. Image layer laser light not obeyed 3. Bite block was not used	1. Check patient positioning with laser light lines and occlusion correction buttons 2. Check patient positioning with laser light lines and occlusion correction buttons 3. Insert bite block

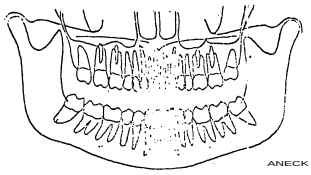
Problem	Possible cause	Remedy
Incisors and canines wide and unsharp. Rows of teeth widened. 	1. Occlusal correction of focal trough set too far anterior 2. Image layer laser light not obeyed 3. Bite block was not used	1. Check patient positioning with laser light lines and occlusion correction buttons 2. Check patient positioning with laser light lines and occlusion correction buttons 3. Insert bite block

Problem	Possible cause	Remedy
Teeth appear wider on one side and narrower on the opposite. Ramus widths are different on opposite sides. 	1. Midsagittal line not obeyed 2. Patient's head not in center position	1. Check patient's mid sagittal plane with laser light line 2. Check that patient's head is centered, and that the head support side clamps where closed to keep the head straight.

Problem	Possible cause	Remedy
The shadow of hard palate is exposed over maxillary molars. Row of teeth has a wavy appearance. TM joints are exposed outward. Image is not "smiling". Mandible is imaged sharper than maxilla. 	Patient head tilted back	Check FH plane

Problem	Possible cause	Remedy
Rows of teeth curved upwards. Mandibular incisors are unsharp. TMJ joints exposed high and are often cut off from the image. Image is "smiling" too much. 	Patient head tilted forward	Check FH plane

Problem	Possible cause	Remedy
Middle area of the image too bright and unsharp. Spine shadow.	Patient's neck was not stretched	Stretch patient's neck



Problem	Possible cause	Remedy
Black shadow over maxillary teeth apex area.	Tongue was not against the roof of palate.	Ask patient to swallow and place tongue against the roof of palate during the exposure.

Problem	Possible cause	Remedy
TMJ's exposed on different heights on image. Bilateral distortion in molar and premolar regions.	1. Patient tilted to one side 2. Midsagittal laser light line not obeyed.	1. Check midsagittal plane and center patient's head. 2. Check midsagittal plane and center patient's head.

Problem	Possible cause	Remedy
Rows of teeth exposed too high. TMJ's cut off.	1. Chin was not resting on chin support 2. Patient positioned too high	1. Check patient positioning and type of bite fork rod. 2. Check patient positioning and type of bite fork rod.

Problem	Possible cause	Remedy
Rows of teeth exposed too low. Mandible not exposed completely to the image.	Chin rest was not used with bite fork.	Install chin rest.

6.2 Image appearance

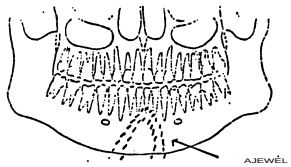
Problem	Possible cause	Remedy
Images are too light	1. CLINIVIEW™: Contrast and brightness not optimum 2. CLINIVIEW™: Gamma not set correctly	1. Adjust contrast and brightness. 2. Select a more fitting histogram type and check gamma setting.

Problem	Possible cause	Remedy
Images are too dark	1. CLINIVIEW™: Contrast and brightness not optimum. 2. Manual technique factors used too high.	1. Adjust contrast and density. 2. Decrease technique factors.

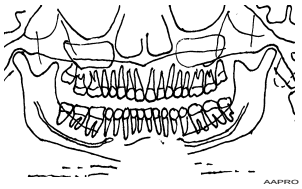
Problem	Possible cause	Remedy
Lack of image contrast	1. CLINIVIEW™: Contrast and brightness not optimum. 2. kV used is too high. 3. Gamma value is not correct for the monitor being used.	1. Adjust contrast and brightness. 2. Lower the kV setting. 3. Adjust Gamma value

6.3 Artefacts

Problem	Possible cause	Remedy
Irregular, bright shadows or artefacts	Patient is wearing metal objects, such as earrings, necklace etc.	Ask patient to remove objects.



Problem	Possible cause	Remedy
An unexposed area is shown down in the lower middle section of the image.	Lead apron misplaced.	Check the lead apron positioning.



Problem	Possible cause	Remedy
Partial lack of detail and motion artefacts. Irregular vertical bright lines on image.	Patient has moved during the exposure.	Retake the image.

Problem	Possible cause	Remedy
Vertical dark lines on image.	Patient's shoulder in touch with machine parts.	Check patient positioning.

Problem	Possible cause	Remedy
Patient's right side tooth are not exposured.	Exposure button released prematurely.	Retake the image.

Problem	Possible cause	Remedy
Right and left image sides are uncomplete. TMJ's are not shown.	Orthogonal procedure was mistakenly used.	Select correct panoramic procedure.

Problem	Possible cause	Remedy
A light horizontal line on QA image.	Bite block was left on place.	Remove the bite block and retake QA image.

Problem	Possible cause	Remedy
Horizontal lines on image.	Sensor problem.	Consult the dealer.

Problem	Possible cause	Remedy
CEPH: Lateral view has 2 ear holder pins.	1. Cephalostat lock not locked 2. Ear holders misaligned	1. Lock it 2. Call service

6.4 Unit operation

Problem	Possible cause	Remedy
Back of the patient's head is touching the x-ray tube during the exposure.	1. Patient's head inclination not correct 2. Patient is too big for the unit. 3. Patient has slumped.	If the image is not acceptable then 1. Check the head position and retake the image. 2. Check the patient positioning. Make the exposure even though the head may touch the tube head. 3. Check the patient positioning. Make the exposure even though the head may touch the tube head.

Problem	Possible cause	Remedy
Patient's shoulders are touching the x-ray tube or sensor.	Patient is too big for the unit. Wide and high shoulders.	Reverse patient's hands on handles: left to right side handle and vice versa.

7 Maintenance

7.1 Maintenance procedure

The maintenance procedure described below shall be seen as a minimum requirement and can be made more stringent to comply with regulations regarding the use and maintenance of dental x-ray devices that are in force in the country in which the unit is installed.

7.1.1 Annual maintenance

An annual maintenance procedure must be carried out at least once a year by qualified service personnel. Contact your local distributor for details.

7.1.2 Calibration intervals

To keep the image quality at best possible level, calibrations and quality checks shall be carried out at regular intervals according to the table below.

Modality	Minimum requirement	Recommendation
3D	Two (2) times annually	Four (4) times annually
Panoramic	Annually during normal maintenance	Two (2) times annually
Cephalometric	Annually during normal maintenance	Two (2) times annually

Note! *The calibrations mentioned in this manual can be done by the user or qualified service personnel.*

7.2 Changing the fuses

Main fuses are located next to the on/off power switch. Push inward on the fuse base and twist it counterclockwise with a screwdriver. The fuse with the base comes out.

Remove the fuse from the base and replace it with the new one. Repeat this with each blown fuse. Fasten both fuses by pushing the base in and twisting it clockwise with a screwdriver.

Use only appropriate fuses:

- Line voltage 220-240 Vac: 326 Littelfuse 10A (slow blow) or Cooper Bussman MDA-10 (time delay)
- Line voltage 100-120 Vac: 326 Littelfuse 15A (slow blow) or Cooper Bussman MDA-15 (time delay)

7.3 Cleaning and decontaminating the unit

CAUTION!

Switch the unit off or disconnect it from mains before cleaning the unit. If you use a spray cleaner do not spray into any ventilation grills. Do not allow water or other cleaning liquids to enter the unit interior since these may cause short-circuits or corrosion. The unit should be cleaned after every usage.

CAUTION!

Clean the dust off the unit regularly. The unit might overheat if excess dust is gathered on the cooling grilles.

Unit surfaces

All surfaces can be wiped clean with a soft cloth dampened with a mild detergent, e.g. soapy water. DO NOT use abrasive cleaning agents or polishes on this equipment.

Positioning light covers

The positioning light covers are made of clear plastic. Use a soft cloth dampened with a mild detergent, e.g. soapy water. NEVER use abrasive cleaning agents or polishes to clean the covers.

Surfaces that the patient touches

All surfaces and parts that the patient touches or comes into contact with must be decontaminated after each patient. Use a disinfectant that is formulated specifically for decontaminating dental equipment and use the disinfectant in accordance with the instructions supplied with the disinfectant. All items and surfaces should be dried before next usage.

Note! *Wear gloves and other protective equipment during decontamination process. In accordance with the instructions supplied with the cleaner.*

WARNING!

Do not use any disinfecting sprays since the vapor could ignite causing injury.

Decontamination techniques for both the unit and the room must comply with all laws and regulations within the local jurisdiction.

Examples of cleaning agents that can be found in disinfectant products which are allowed or prohibited **when cleaning the unit**:

Allowed: Methanol (metyl alcohol), Soap, Isopropyl alcohol, distilled water.

Not allowed: Bentzene, Chlorine bentzene, Acetone, Acetic ether, agents containing phenol, paracetic acid, peroxide and other oxygen-cleaving agents, sodium hypochlorite and iodine-cleaving agents.

Autoclave

Some removable parts in contact with the patient may be autoclaved. These parts are: bite rods, bite guides and chin supports.

If autoclaving is performed for these items, disinfection by alternate methods is not needed.

Steam sterilization

Recommended parameters for sterilizable parts are:

- Gravity-displacement steam sterilization

  "Flash" sterilization:
  Temperature: 270 F (132°C)
  Exposure time: 3 minutes

- Prevacuum steam sterilization

  "Flash" sterilization:
  Temperature: 270 F (132°C)
  Exposure time: 3 minutes

- Steam-flush pressure-pulse steam sterilization

  Temperature: 270 F to 275 F (132°C to 135°C)
  Exposure time: 3 to 4 minutes

8 Calibration and adjustment

8.1 Introduction

Calibrations and quality checks are performed by taking exposures of calibration tools. The system does needed adjustments according to the image data captured. For panoramic and cephalometric quality checks the quality is visually evaluated by the operator.

Resulting from the each calibration is an image containing calibration results, telling the operator how to proceed with the calibration and adjustment procedure. In addition to the calibration name (e.g. Adjustment panCol) the images contain image data sampled during the calibration, adjustment instructions and a "Passed / Not Passed / Failed" calibration status.

- **Passed** means that the calibration program is successfully done. Move on to next calibration.
- **Not passed** means that adjustment is still needed. Follow the instructions the image (if any) and take another exposure. Some calibration programs are iterative and demand a few repetitions.
- **Failed** means that the system could not decide what adjustment should be done in order for the calibration to succeed. This calibration status is always the result of some error condition. Taking another exposure will not help. The image may give a hint on what the problem is (e.g. no radiation, collimator severely tilted, image data corrupted…). Contact service if the problem persists after restarting the unit and PC.

8.2 Preparing for calibration

1. Close the head support and lock it in its upmost position.

2. Switch the PC and unit on.

3. **PC:** Open the dental imaging software and then open a patient (card) and give it and identifiable name, for example: calibration (refer to the user's manual supplied with the dental imaging software for more information).

4. **PC:** Click the image acquisition button to activate image capture.

5. Touch the **settings** button on the touch screen display.

6. Select the **Quality assurance** button.
   The calibration display appears.

8.3 Panoramic calibration

8.3.1 Panoramic geometry calibration

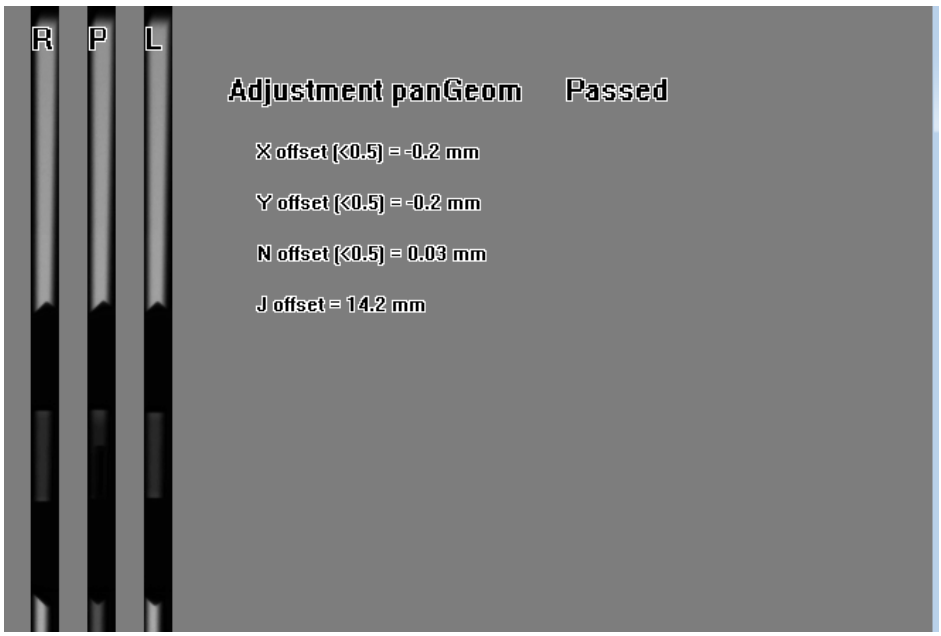
1. Select the program.

2. Press **Patient Positioning**.

3. Install the double cone calibration tool.

4. Take an exposure.

5. Repeat the calibration until calibration result “passed” is achieved.



8.3.2 Panoramic pixel calibration

Note! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

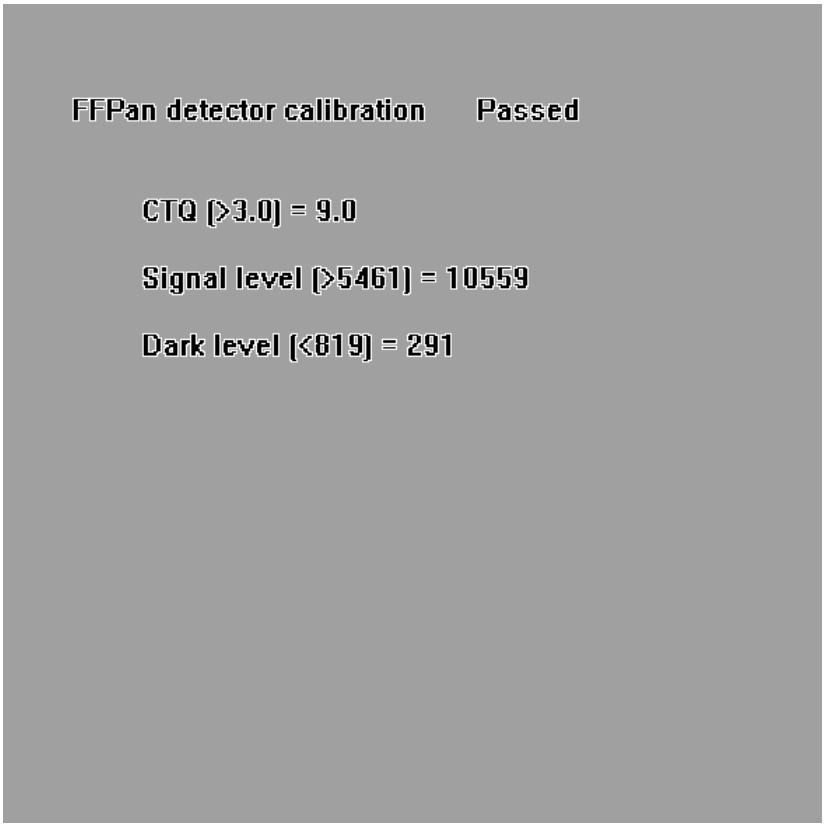
Note! *Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.*

1. Remove the double cone calibration tool.

2. Select the program.

3. Press **Patient Positioning**.

4. Take an exposure.



8.3.3 Panoramic Quality Check (optional)

Note! *Use the same tool for cephalostat Quality Check.*

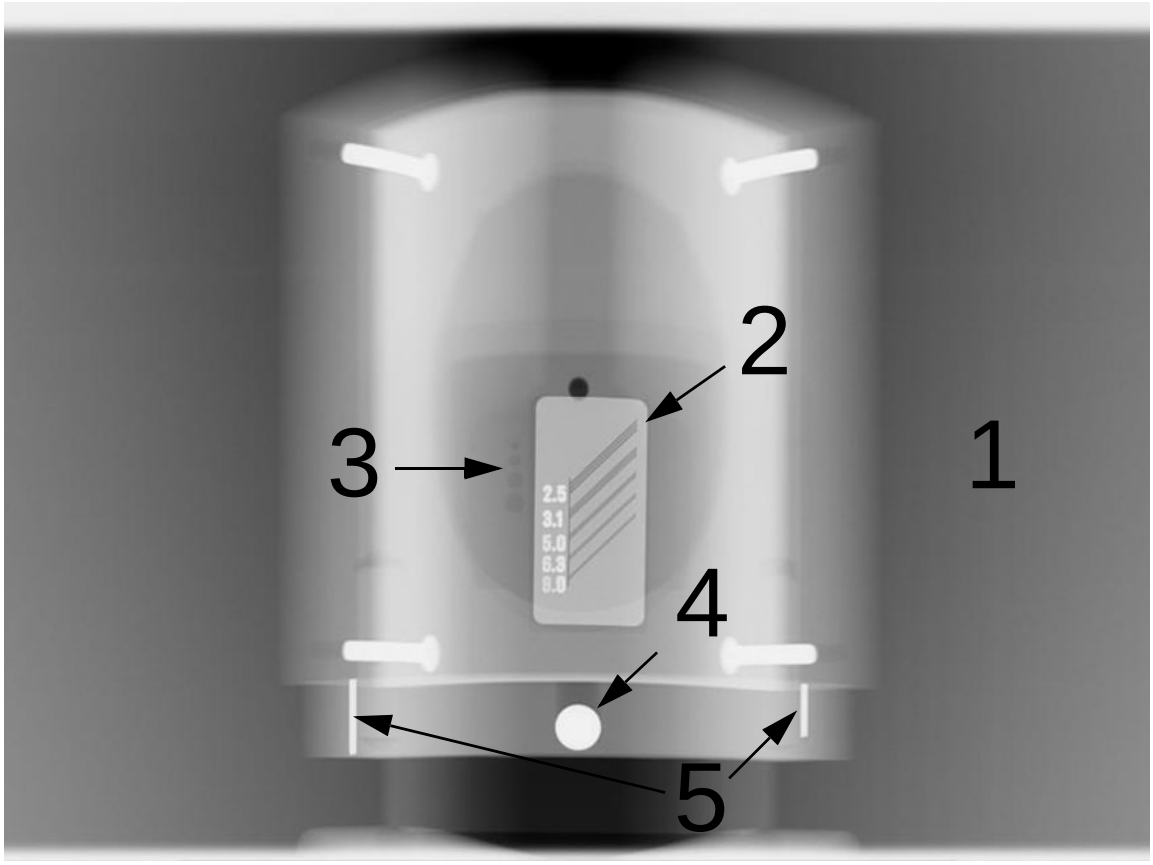
1. Attach a panoramic Quality Check Tool (optional) to the chin support.

2. Select the Pan QC program.

3. Press **Patient Positioning**.

4. Take an exposure.

5. Visually evaluate the result using the installed imaging software.



Subjects to be evaluated:

1. Smoothness of the exposed area. Non-exposed area surrounds the whole image.

2. High contrast resolution; minimum 3.1LP/mm must be distinguishable.

3. All four low contrast holes must be visible.

4. Roundness of the ball. The ball should be placed symmetrically between the two pins (5). Other pin is longer than the other.

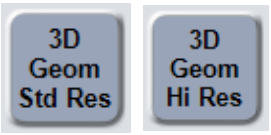
Note! *The panoramic QC collimator is equipped with a 0.8 mm copper filter. If more filtration is required, additional filtration may be attached to the tubehead cover. The unit may be configured to use higher exposure values to compensate for an additional 1 mm copper filter.*

Ask Technical Support to adjust the copperthickness setting as required.

8.4 3D calibration

8.4.1 3D geometry calibration

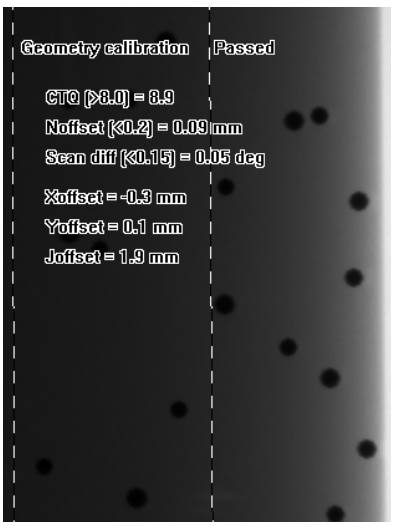
1. Attach the base of the phantom to the lower shelf. Level it with the bubble.



2. Select the program.There is a calibration procedure for both 3D imaging modes, standard and high resolution. Standard geometry calibration has to be done first.

3. Press **Patient Positioning**.

4. Install the 3D calibration phantom.



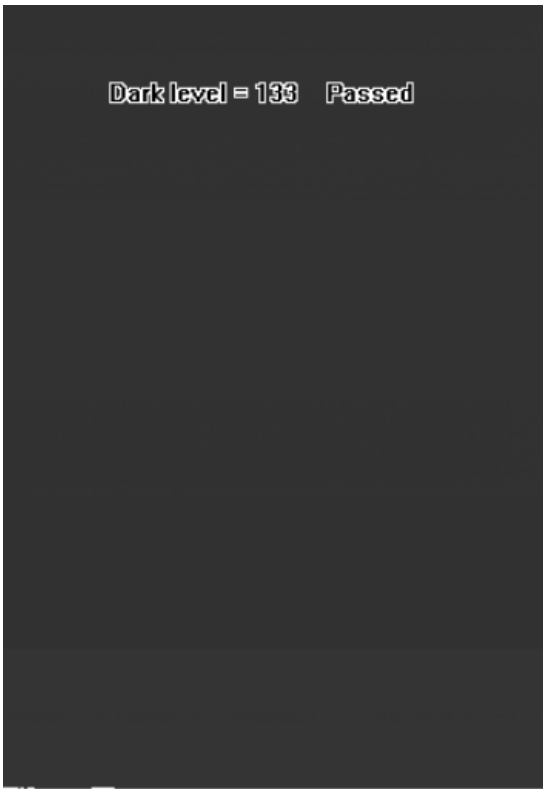
5. Take an exposure.

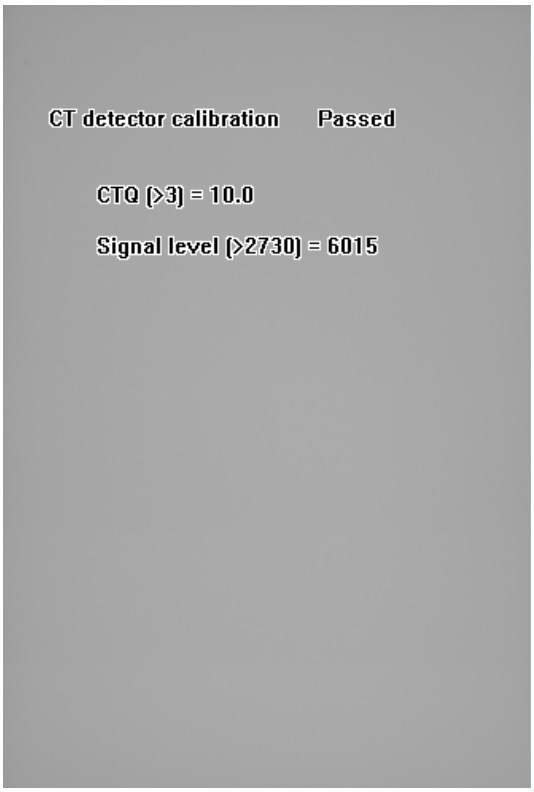
6. Repeat the calibration until calibration result “passed” is achieved. This calibration is only needed with 3D units.

8.4.2 3D pixel calibration

1. Remove the 3D calibration phantom.
2. Select the program.

3. Press **Patient Positioning**.
4. Take an exposure. The result image informs when the calibration is passed.





8.4.3 3D Quality Check program

1. Attach the QC phantom to the unit.

2. Select the 3D QC program.

3. Press **Patient Positioning**.

4. Take an exposure.

5. The resulting image contains information on whether the quality check was passed.

8.5 Cephalometric calibration

8.5.1 Ceph pixel calibration

Note! *The pixel calibration results are sensor specific. If the x-ray unit is equipped with separate panoramic and cephalometric sensors, the cephalometric sensor cannot be used for panoramic imaging without re-calibration (and vice versa).*

Note! *Re-do panoramic pixel calibration, if cephalostat sensor is moved to panoramic side or the sensor is changed.*

1. Rotate the ear holders into PA view position and move them completely apart. Turn nasion support up out of the way.

2. Select Ceph Pix program.

3. Press **Patient Positioning**.

4. Take an exposure.

5. This calibration should always be a pass.

8.5.2 Ceph Quality check program (Optional)

Note! *Rotate the ear holders into PA view position. Turn nasion support up out of the way.*

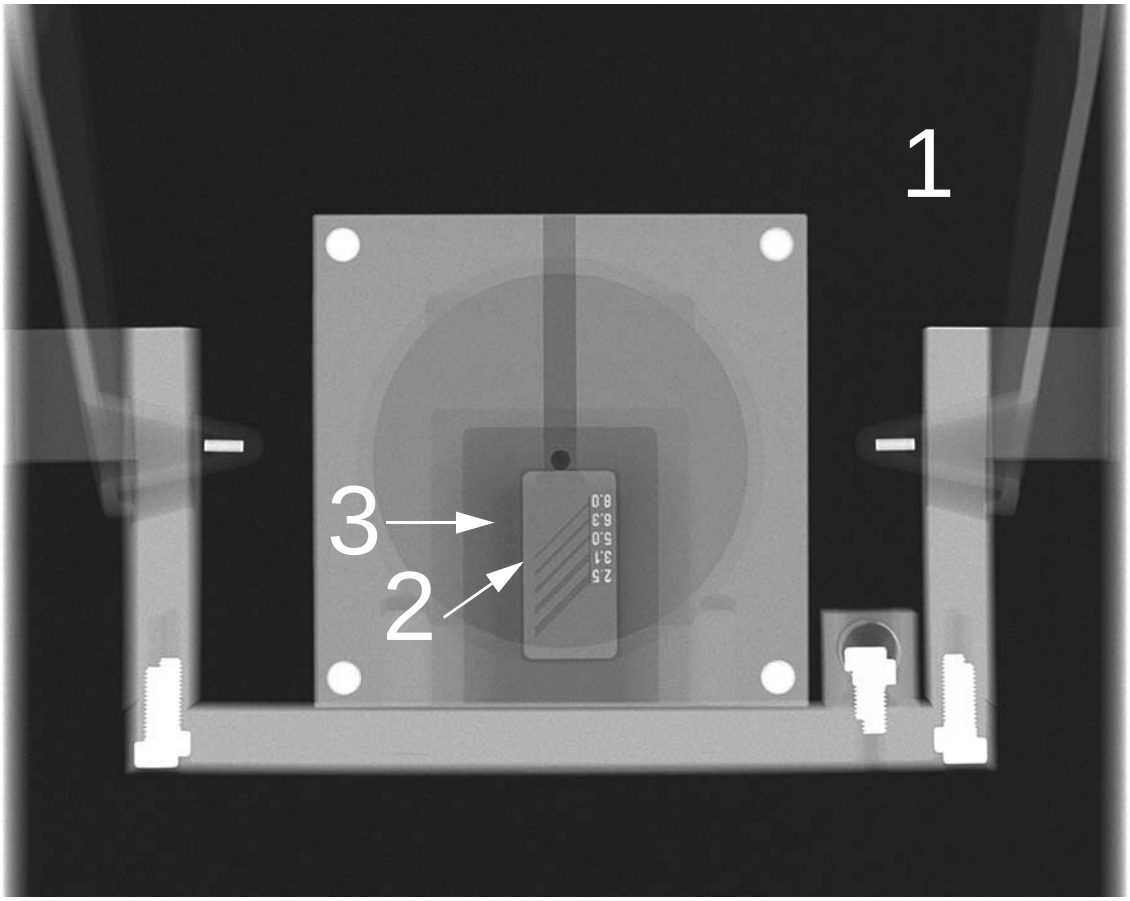
1. Attach the QC phantom to the ceph unit and ensure that it's leveled from the spirit level.

2. Select the Ceph QC program.

3. Press **Patient Positioning**.

4. Take an exposure.

5. *Visually evaluate the result using the installed imaging software.*



Subjects to be evaluated:

1. Smoothness of the exposed area. Non-exposed area surrounds the whole image.

2. High contrast resolution; minimum 3.1LP/mm must be distinguishable.

3. All four low contrast holes must be visible.

9 Technical data

9.1 Technical specifications

Manufacturer	Instrumentarium Dental, Nahkelantie 160 (P.O. Box 20) FIN-04300 Tuusula, FINLAND
Quality system	In accordance with ISO13485 and ISO9001 standard
Environmental management system	In accordance with ISO14001 standard
Conformity to standards:	IEC 60601-1: 1988 and A1+A2 IEC 60601-1-1: 2000 IEC 60601-1-4: 1996 and A1 IEC 60601-2-7: 1998 IEC 60601-2-28: 1993 IEC 60601-2-32: 1994 IEC 60601-1-2: 2001 and A1 IEC 60601-1-3: 1994 UL 60601-1: 2003 CAN/CSA –C22.2 No. 601-1-M90 and S1+A2 standards This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture. OP300 is in conformity with the provisions of Council Directive 93/42/EEC as amended by the Directive 2007/47/EC concerning medical devices. Performance Standards and European Union Directive 93/42/EEC (Medical Devices Directive).

Product name	**ORTHOPANTOMOGRAPH® OP300**
Model:	OP300
Product type:	Digital dental imaging system with panoramic cephalometric and Cone Beam 3D imaging programs.

Unit data	
Protection against electric shock	Class I
Degree of protection	Type B applied with no conductive connection to the patient
Protection against the ingress of liquids	IP20
Disinfection methods	- mild soapy water (non-abrasive) - non-alcohol based disinfectant for the chin rest - disposable plastic covers for bite block, chin rest and chin support
For use	In environments where no flammable anaesthics nor flammable cleaning agents are present
Mode of operation	continuous operation/intermittent loading
Safety	IEC 60601-1
EMC Classification	Class B

Tube head assembly	
Tube head assembly type	THA 300
Tube type	Toshiba D-052SB, D-054SB-C Stationary anode
Tube voltage	57 - 90 kV
Max. tube current	16 mA
Max. electric output	1,44 kW
Target angle	5 degrees
Focal spot	0,5 x 0,5 mm (IEC 336/1982)
Nominal anode input	1750 W
Reference axis	In the middle of the panoramic sensor´s active area
Max. anode heat content	35 kJ
Max. X-ray tube assembly heat content	385 kJ
Max. continuous heat dissipation of the X-ray tube assembly	38 W
Total filtration	>3,2 mm Al
Leakage Technique Factors	90 kV /4 mA

Electrical connections	
Nominal mains voltage	100 - 240 Vac (Selectable)
Input power frequency	50 / 60 Hz
Nominal current	10A @ 230 VAC, 15A @ 110 VAC
Fuses	230 Vac: Littelfuse 326 (slow blow) 10A Cooper Bussman (time delay) MDA-10 110 Vac: Littelfuse 326 (slow blow) 15A Cooper Bussman (time delay) MDA-15
Power consumption	2.3 kVA @ 230 VAC, 1.65 kVA @ 110 VAC
Maximum impedance of main	0,2 Ω

2D modalities

The following charts represent technique factors that can be used with the selected line voltage and continuous radiation. One of the three technique factors is always fixed.

Table 1: 100 VAC											
mA											
16											
13	x	x	x								
10	x	x	x	x	x	x	x				
8	x	x	x	x	x	x	x	x	x	x	
6	x	x	x	x	x	x	x	x	x	x	
4	x	x	x	x	x	x	x	x	x	x	
	57	**60**	**63**	**66**	**70**	**73**	**77**	**81**	**85**	**90**	**kV**

Table 2: 120 VAC											
mA											
16	x	x	x								
13	x	x	x	x	x	x	x	x			
10	x	x	x	x	x	x	x	x	x	x	
8	x	x	x	x	x	x	x	x	x	x	
6	x	x	x	x	x	x	x	x	x	x	
4	x	x	x	x	x	x	x	x	x	x	
	57	**60**	**63**	**66**	**70**	**73**	**77**	**81**	**85**	**90**	**kV**

Table 3: 240 VAC											
mA											
16	x	x	x	x	x	x	x				
13	x	x	x	x	x	x	x	x	x	x	
10	x	x	x	x	x	x	x	x	x	x	
8	x	x	x	x	x	x	x	x	x	x	
6	x	x	x	x	x	x	x	x	x	x	
4	x	x	x	x	x	x	x	x	x	x	
	57	**60**	**63**	**66**	**70**	**73**	**77**	**81**	**85**	**90**	**kV**

3D modalities

The following charts represent technique factors that can be used with the selected line voltage in 3D imaging mode. 3D modality uses pulsed x-rays with fixed kV and exposure time.

Table 4: 100 VAC @ 90 kV 120 VAC @ 90 kV 240 VAC @ 90 kV				
mA				
13	x	x	x	
10	x	x	x	x
8	x	x	x	x
6	x	x	x	x
4		x		x
	6 x 4 std res	**6 x 4 high res**	**6 x 8 std res**	**6 x 8 high res**

Positioning laser lights	
Panoramic, TMJ & Maxillary Sinus Programs Cephalostat FH laser light 3D imaging programs	laser light (CLASS 1 LASER PRODUCT) max output 100µW Warning symbols are placed next to the laser lights and the label describing the laser light classification is placed inside the carriage side cabinet. USA / Canada models have different types of laser light stickers according to local requirements. Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
	IEC 60825-1:1993+A1:1997+A2:2001

X-ray generator	
Nominal power	1750 W nominal at 90 kV, 12 mA
Tube voltage	57 - 90 kV (+/- 5 kV)
Tube current	3,2 - 16 mA (+/- 1 mA)
Supply frequency	75 - 150 kHz
Spine compensation	kV / mA compensated
Spine compensation mode	Pre-programmed

User interface	
Program and technique factors selection, exposure control	Touch screen panel, optional remote exposure switch
Patient positioning	Positioning panel, integrated
Connection cable (OP300 - PC)	CAT6 Ethernet cable

Panoramic programs & technique factors & magnification:		
Standard Adult Panoramic	57-90 kV/ 3.2-16 mA/16.4 s	30%
Pediatric Panoramic	57-90 kV/ 3.2-16 mA/14.4 s	30%
Ortho Zone	57-90 kV/ 3.2-16 mA/17.9 s	25%
Orthogonal Panoramic	57-90 kV/ 3.2-16 mA/12.9 s	30%
Wide Arch Panoramic	57-90 kV/ 3.2-16 mA/16.2 s	30%
Ortho TMJ	57-90 kV/ 3.2-16 mA/10.6 s	23%
PA TMJ View	57-90 kV/ 3.2-16 mA/10.6 s	55%
Maxillary Sinus	57-90 kV/ 3.2-16 mA/12.5 s	30%
Bitewing	57-90 kV/ 3.2-16 mA/11.9 s	30%
Panoramic QC	57-90 kV/ 3.2-12.6 mA/16.4 s	30%

Exposure Control	Pre-programmed icons for all programs Automatic Spine Compensation	

Cephalometric programs & technique factors:	
Pediatric lateral view	85-90 kV / 8-12.6 mA / 6.9-14 s
Lateral view	85-90 kV / 8-12.6 mA / 10-20 s

Cephalometric programs & technique factors:	
PA/AP, facial and oblique views	85-90 kV / 8-12.6 mA / 10-20 s
Carpus View (Not available in USA and Canada)	60-90 kV / 3.2-12.6 mA / 8-20 s
Exposure Control	Automatic Facial Contour (AFC), Pre-programmed icons for all programs.
Magnification factor	1.15 (15%)

3D imaging programs:	
Small FOV dimensions	61 x 41 mm (HxD)
Large FOV dimensions	61 x 78 mm (HxD)
Small FOV standard resolution	90 kV / 6.3 - 12.5 mA / 2.3 s
Large FOV standard resolution	90 kV / 6.3 - 12.5 mA / 4.9 s
Small FOV high resolution	90 kV / 4 - 12.5 mA / 6.1 s
Large FOV high resolution	90 kV / 4 - 10 mA / 12.6 s
Small FOV scout	90 kV / 4 - 12.5 mA / 0.02 s
Large FOV scout	90 kV / 4 - 12.5 mA / 0.04 s

Image storing and retrieving:	
File formats	PNG (16-bit), JPG (12-bit)
File compression	PNG (lossless), JPG (100%-60% quality)
Typical panoramic file size	About 2-4 MB (PNG 16 bits)
Typical cephalometric file size	3-5 MB (PNG 16 bits)
Typical 3D file size	150-250 MB (DICOM)
Patient database	Standalone workstation Server on local area network (LAN)

Panoramic patient positioning	
Operation	Left or right side of unit Motorised carriage movement
Positioning aids	Chin rest, bite block, 3-point headrest Curved mirror, 3 positioning laser lights, Occlusion correction buttons

Cephalostat patient positioning	
Operation	Arm mounts on left or right side of the unit Interlocked pan/ceph sensor Motorised carriage buttons at cephalostat head assembly.
Positioning aids	Ear holders, Nasion support with vertical mm scale, Frankfort horizontal plane laser light, Contact plate (Carpus program).

3D imaging patient positioning	
Operation	Left or right side of unit Motorised carriage movement
Positioning aids	Chin rest, chin support, 3-point headrest, Curved mirror, 3 positioning laser lights

Cephalostat scanning	
Scanning method	Horizontal scan, synchronized sensor and secondary slot motion
Scanning time	10 - 20 s.

Panoramic image receptor	
Sensor unit	Pan sensor or interchangeable Ceph sensor
Technology	CMOS
Image pixel size	100 x 100 μm
Active area height	5.8 inches / 148 mm / 1480 pixels
Resolution	Pan: 5 LP/mm

Cephalometric image receptor	
Sensor unit	interchangeable Ceph sensor
Technology	CMOS
Image pixel size	100 x 100 μm
Active area height	223,2 mm / 2232 pixels
Image field width in lateral view	10.2 inches / 260 mm, maximum 6.7 inches / 170 mm, minimum
Image field width in PA view	7.9 inches / 200 mm
Resolution	4 LP/mm (cephalometric)

3D image receptor	
Sensor unit	3D sensor
Technology	CMOS
Image pixel size	200 x 200 μm
Photodiode area:	100 x 68.2 mm

Unit physical measures:	
source-image distance (SID)	500 mm (Panoramic) 570 mm (3D)
Installation	Standard wall mount with ±45° angled joint. Optional base for free standing unit (unit height is increased 25 mm).
Height x Width x Depth (inches/mm)	2410x830x1126mm (standard column) 94.9 x 32.7 x 44.3 inches -Max.
Weight	200 kg / 441 lbs. (Panoramic)

OP300 ceph physical measures:	
source-image distance (SID)	68.7 inches / 1745 mm
source-object distance (SOD)	60 inches / 1520 mm
Installation	Standard wall mount with 45° angled joint. Optional base for free standing unit (unit height is increased 25 mm)
Height x Width x Depth (inches/mm)	2410 x 1931 x 1193 mm 94.9 x 76 x 47 inches
Weight	240 kg / 529 lbs. (Cephalometric)

Ambient temperatures:	
Transportation and Storage	-10°…+60°C
Operation Temperature	+10°...+35°C, RH max. 85%

Minimum PC requirements for 3D acquisition workstation	
Processor	2.5 GHz dual core, or better
Memory	3 Gigabytes RAM, or more
Hard disk	500 GB, or more
Power supply	500 watt minimum
Network	Gigabit Ethernet 1000Base-T
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Display	20" LCD display, 1600 x 1200 or 22" LCD widescreen display, 1680 x 1050, or better
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Graphics board	The system is highly dependent on the used graphics board and graphics driver of the reconstruction workstation. Consult technical support for information on the supported boards and drivers. Examples of supported boards: NVidia Quadro 4000 NVidia GeForce GTX 560 The compatible graphics driver versions are found on the driver update DVD.
PCI board connection	Full-length PCIe x16 slot (for GPU board)

Minimum PC requirements for 3D acquisition workstation	
USB	USB ports (for HASP Dongle keys) • 1 for reconstruction system • 1 for 3D viewing SW (if needed)
Mouse	Mouse with scroll wheel

Minimum PC requirements for 2D acquisition workstation *	
Processor	2.5 GHz dual core, or better
Memory	3 Gigabytes RAM, or more
Hard disk	500 GB, or more
Graphics board	NVidia GeForce 6600 or ATI Radeon X700 or better; 256MB or more memory (integrated graphics are not supported)
Power supply	500 watt minimum
Network	Gigabit Ethernet 1000Base-T
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Display	20" LCD display, 1600 x 1200 or 22" LCD wide screen display, 1680 x 1050, or better
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Mouse	Mouse with scroll wheel
OpenCL support	OpenCL 1.1 supported by either processor or graphics adapter

* These requirements are valid only if driver update 11.4 or later is used. For earlier versions see table Minimum PC requirements for 3D acquisition workstation.

Note! *This is an abbreviated list of requirements. Please refer to the software installation manual or contact your local dealer for detailed installation requirements.*

Minimum PC requirements for 2D/3D Viewing workstation *	
Processor	2.0 GHz dual core, or better
Memory	2 Gigabytes RAM, or more
Graphics board	NVIDIA GeForce 6600 or ATI Radeon X700 or better; 256MB or more memory (integrated graphics are not supported)
Hard disk	3 GB free space, or more
Network	Gigabit Ethernet 1000Base-T (recommended) or Fast Ethernet 100Base-TX
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Display	19" LCD display, 1280 x 1024, or better

* For the PC requirements of the 3D viewing software consult the 3D software manuals.

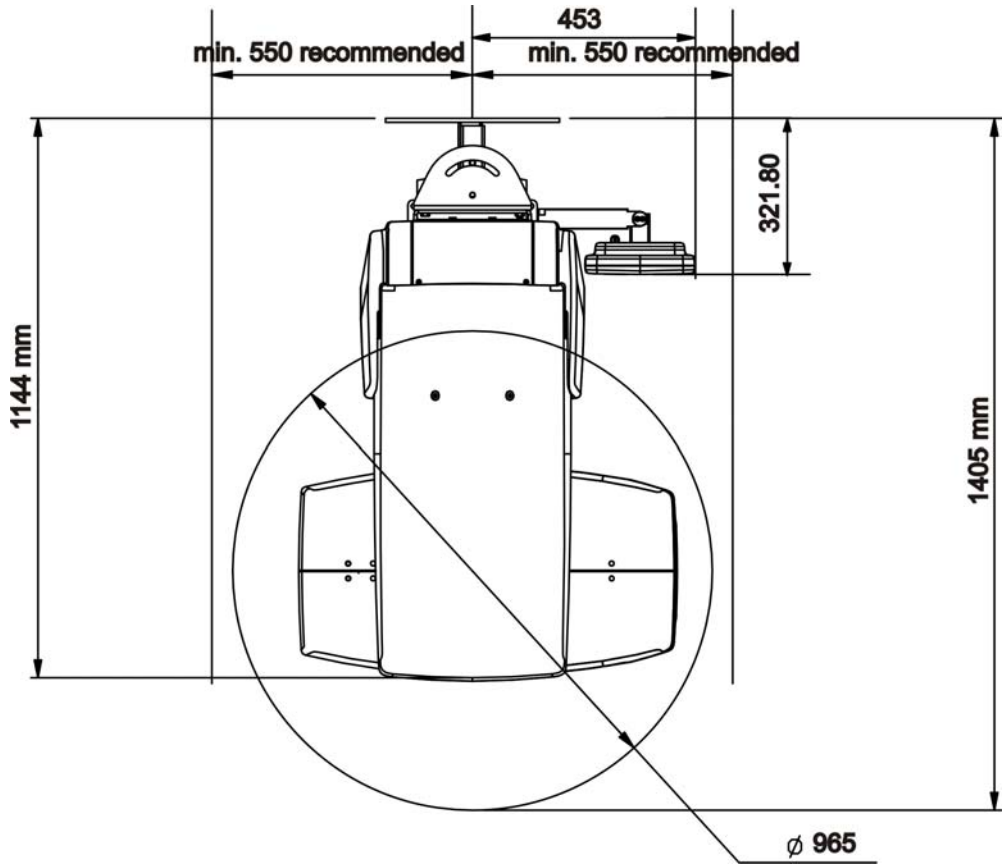
System requirements and connections

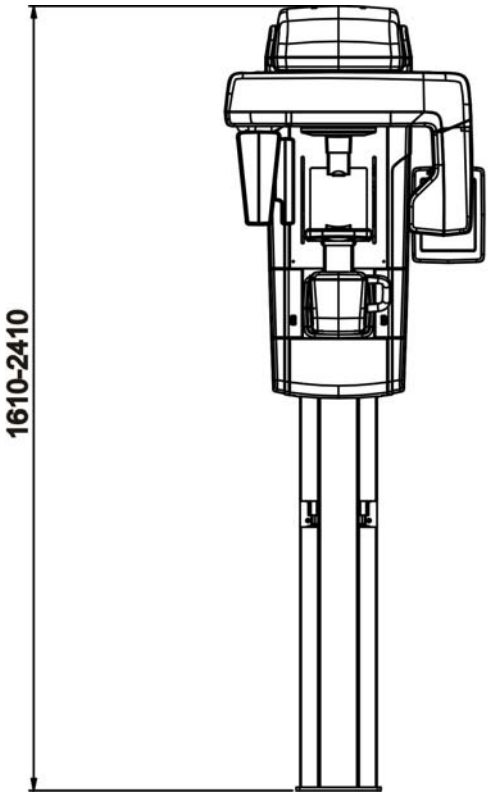
- The PC and any other external device(s) connected to the system must meet the IEC 60950 standard (minimum requirements). Devices that do not meet the IEC 60950 standard must not be connected to the system as they may pose a threat to operational safety.
- The PC and any other external devices must be connected in accordance with IEC 60601-1-1.
- The x-ray unit must be connected to it’s own separate power supply. The PC and any other external devices must NOT be connected to the same power supply as the x-ray unit.
- Position the PC and any other external device at least 1.5 m (60”) from the xray unit so that the patient cannot touch the PC or any other external device while being x-rayed.
- The PC and any other external devices shall not be connected to an extension cable.
- Multiple extension cables shall not be used.
- Do not position the PC where it could be splashed with liquids.
- Clean the PC in accordance with the manufacturer’s instructions.

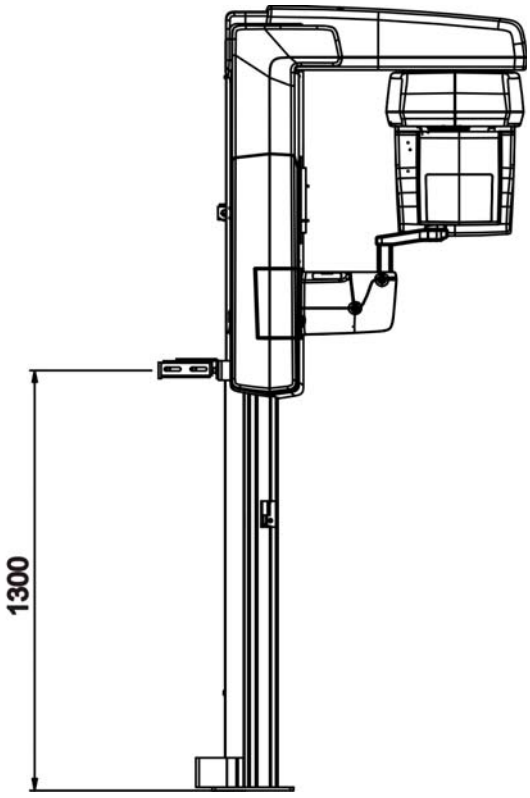
Ceph ready option (Ordered separately)	
Options	**Description**
Interchangeable Ceph sensor with OP300 pan unit	Unit has the same sensor as ceph unit. Cost saving with future digital ceph upgrade.

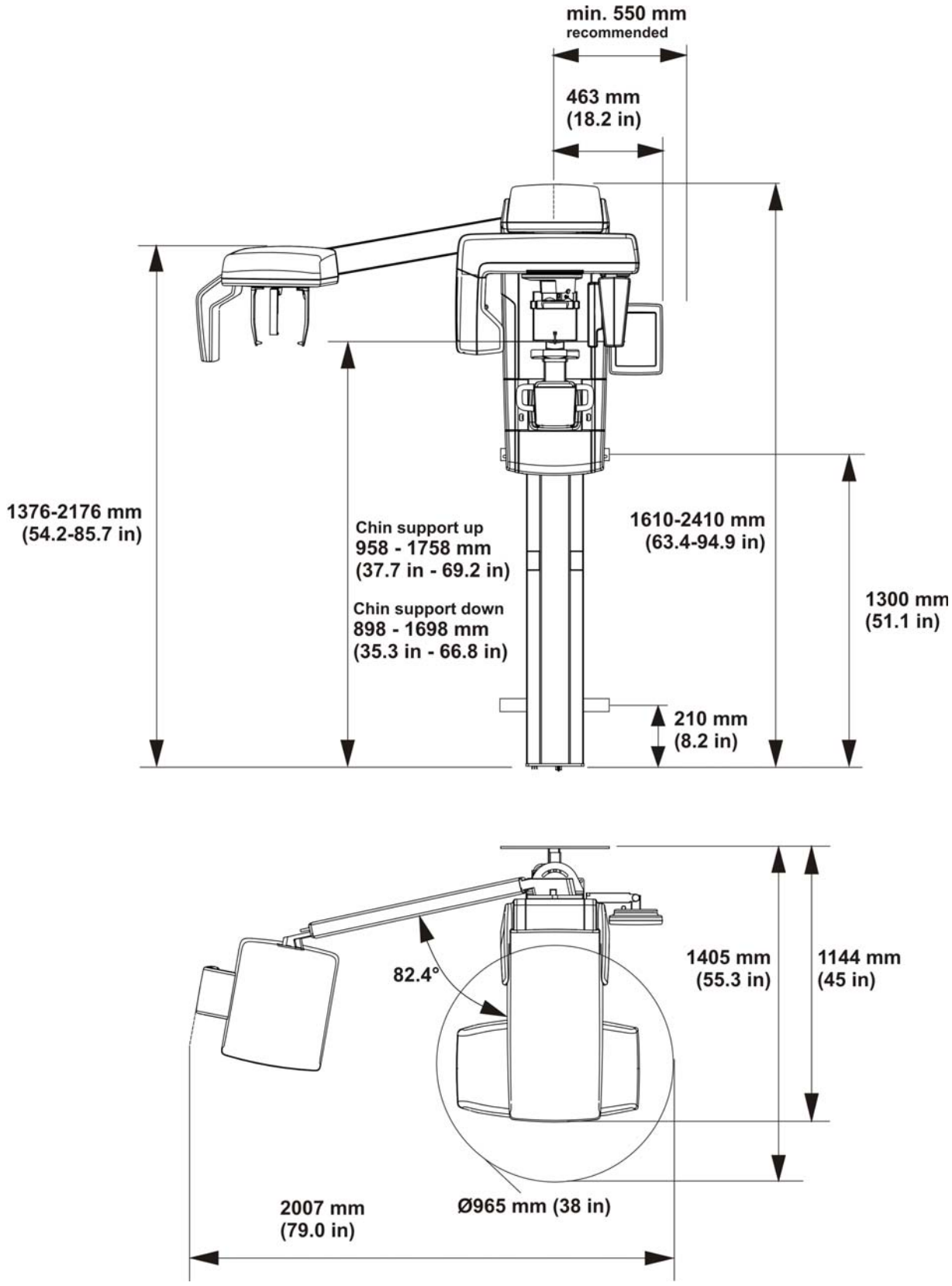
Field upgrades for model OP300	
Upgrade	**Description**
Digital Cephalostat Kit	Add digital ceph imaging to OP300 digital pan
3D Upgrade Kit	Add 3D option to OP300

9.2 Unit dimensions








min. 550 mm
recommended
463 mm
(18.2 in)
1376-2176 mm
(54.2-85.7 in)
Chin support up
958 - 1758 mm
(37.7 in - 69.2 in)
Chin support down
898 - 1698 mm
(35.3 in - 66.8 in)
1610-2410 mm
(63.4-94.9 in)
1300 mm
(51.1 in)
210 mm
(8.2 in)
82.4°
1405 mm
(55.3 in)
1144 mm
(45 in)
2007 mm
(79.0 in)
Ø965 mm (38 in)

9.3 Symbols that appear in the unit

Radiation warning

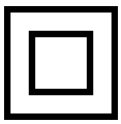
Dangerous voltage

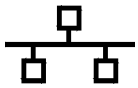
On or enabled

Off or disabled

Exposure switch

Connector for exposure switch


CLASS II equipment
(Double insulated electrical appliance)


Ethernet connector

Operating instruction
(More details in operation instructions)

Laser radiation

Attention, consult accompanying documents

Ground (Functional)

Protective ground

Laser class label (Patient positioning lights)

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

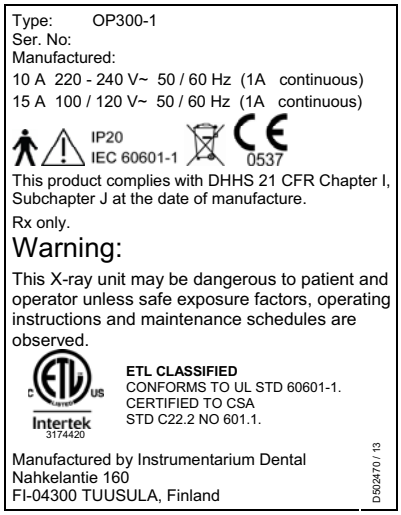
Type B equipment

CE (0537) symbol
MDD 93/42/EEC

ETL Classified conforms to UL STD 60601-1.
Certified to CSA.

9.4 Labels on the unit

The main label of the unit is located on the vertical carriage next to the on/off power switch. The unit is class I, type B and with IP20 protection.


Type: OP300-1
Ser. No:
Manufactured:
10 A 220 - 240 V~ 50 / 60 Hz (1A continuous)
15 A 100 / 120 V~ 50 / 60 Hz (1A continuous)
IP20
IEC 60601-1
0537
This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture.
Rx only.
Warning:
This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.
ETL CLASSIFIED
CONFORMS TO UL STD 60601-1.
CERTIFIED TO CSA
STD C22.2 NO 601.1.
Intertek
3174420
Manufactured by Instrumentarium Dental
Nahkelantie 160
FI-04300 TUUSULA, Finland
D502470 / 13

9.5 Electromagnetic Compatibility (EMC) tables

Note! *Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.*

Table 1.1 Electromagnetic emissions IEC 60601-1-2 Ed2

ORTHOPANTOMOGRAPH® OP300 is suitable for use in the specified electromagnetic environment. The purchaser or user of ORTHOPANTOMOGRAPH® OP300 should assure that it is used in an electromagnetic environment as described below:		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Radio-Frequency Emissions CISPR11	Group 1	ORTHOPANTOMOGRAPH® OP300 uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR11	Class B	ORTHOPANTOMOGRAPH® OP300 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	IEC 61000-3-2 Class A	ORTHOPANTOMOGRAPH® OP300 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	ORTHOPANTOMOGRAPH® OP300 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 1.2 Electromagnetic immunity IEC 60601-1-2 Ed2

ORTHOPANTOMOGRAPH® OP300 is suitable for use in the specified electromagnetic environment. The purchaser or user of ORTHOPANTOMOGRAPH® OP300 should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality is that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality is that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT)	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT)	Mains power quality is that of a typical commercial and/or hospital environment. If the user of ORTHOPANTOMOGRAPH® OP300 requires continued operation during power mains interruptions, it is recommended that ORTHOPANTOMOGRAPH® OP300 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 1.3 RF immunity of non-life-support equipment or system IEC 60601-1-2

ORTHOPANTOMOGRAPH® OP300 is suitable for use in the specified electromagnetic environment. The purchaser or user of ORTHOPANTOMOGRAPH® OP300 should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6 Radiated RFIEC 61000-4-3	3 V150 kHz to80 MHz 3 V/m80 MHz to2,5 GHz	[V1] 3 V [E1] 3 V/m	Portable and mobile RF communications equipment are used no closer to any part of ORTHOPANTOMOGRAPH® OP300, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:

*Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe ORTHOPANTOMOGRAPH® OP300 to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating ORTHOPANTOMOGRAPH® OP300.

Over the frequency range 150 kHz to 80 MHz, field strengths are less than [V1] V/m. The Recommended Separation Distances are listed in the next table.Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Note! *RF communications equipment can effect medical electrical equipment.*

Note! *This equipment generates, uses and can radiate radio frequency energy. If not installed and used in accordance with this manual, it may cause harmful interference to radio communications. Portable and mobile RF communications equipment can also affect the performance of OP300.*

Table 1.4 Table 4

Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
Frequency of Transmitter Equation Rated Maximum Output Power of Transmitter (watts)	150KHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ Separation Distance (meters)	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$ Separation Distance (meters)	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ Separation Distance (meters)
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,34
10	3,69	3,69	7,38
100	11,67	11,67	23,34

USE LIMITATION:

External components

The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of the EQUIPMENT and/or SYSTEM

INSTALLATIONS REQUIREMENTS & ENVIRONMENT CONTROL:

In order to minimize interference risks, the following requirements shall apply.

Cables shielding & grounding

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

Electrostatic discharges environment & recommendations

In order to reduce electrostatic discharge interference, a charge dissipative floor should be installed to prevent charge accumulation.

- The dissipative floor material must be connected to the system reference ground, if applicable.
- Relative humidity must be maintained above 30 percent.

Stacked components & equipment

The ORTHOPANTOMOGRAPH® OP300 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the ORTHOPANTOMOGRAPH® OP300 should be observed to verify normal operation in the configuration in which it will be used.

Interference may occur in the vicinity of equipment marked with the following symbol:

No portable or mobile RF communications equipment may be used closer to any part of the ORTHOPANTOMOGRAPH® OP300, including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.
See Table 4.

9.6 X-ray tube assemblies

Duty cycle 1:8

Rectification type: Constant pot ential x-ray generator

Generator rating: Generator nominal power 1750W

Figure 1.4

Anode Thermal Characteristics

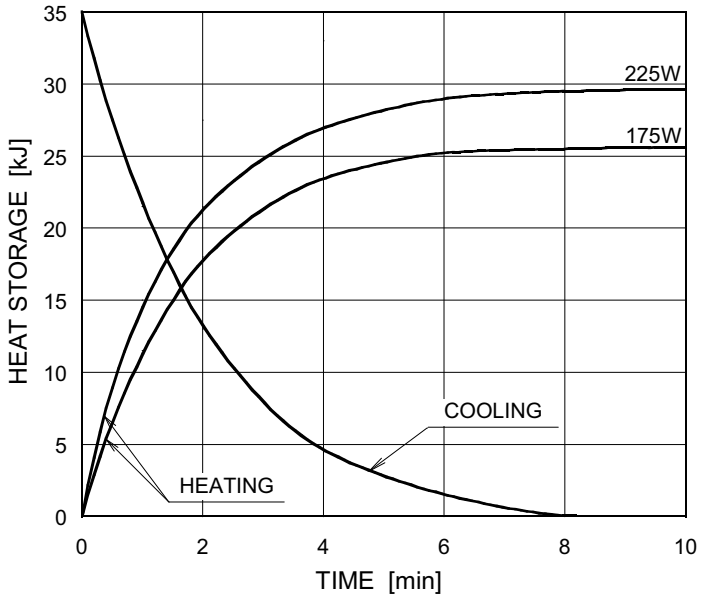


Figure 1.5

Maximum Rating Charts

(Absolute maximum rating charts)

DC (Center-Grounded)

Focal Spot : 0.5 mm

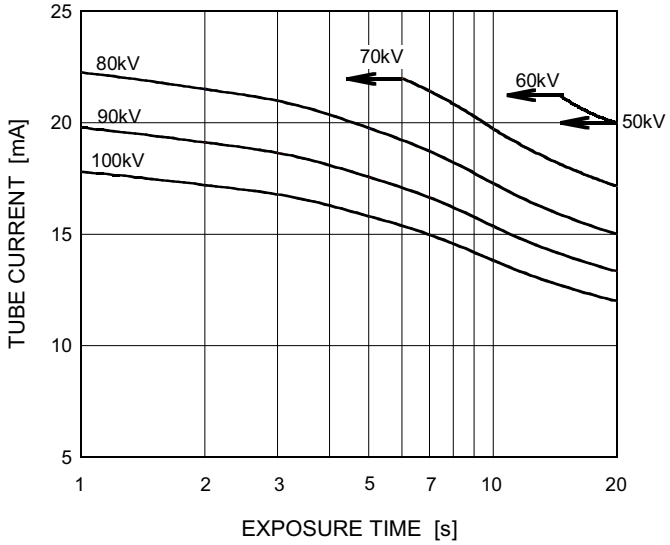
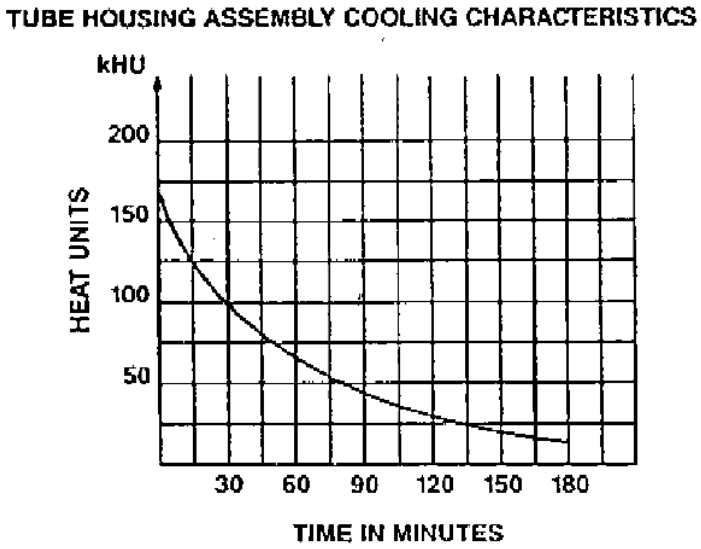


Figure 1.6


TUBE HOUSING ASSEMBLY COOLING CHARACTERISTICS
kHU
200
150
100
50
HEAT UNITS
30
60
90
120
150
180
TIME IN MINUTES